

US3172406 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:31:26

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US3172406

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Participant ID

US3172406

[mRNA-1273-P301 Completion Guidelines](#)

US3172406

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	19 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 13:42:06

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Date of Informed Consent (<i>dd MMM yyyy</i>)	19 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 13:42:07

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Condition	PRESBYOPIA
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Condition	HEAVY MENSTRUAL BLEEDING (RELATED TO UTERINE FIBROIDS)
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Condition	CHRONIC GASTRITIS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Condition	OBESE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Condition	GENERALIZED OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Condition	RIGHT SECOND TOE FRACTURE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Condition	ASPIRIN ALLERGY (HYPOTENSION) (NO ANAPHALAXIS)
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Condition	PARTIAL HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Condition	RIGHT 2ND TOE FRACTURE SURGERY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

US3172406

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	19 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	12:50 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 12:50
Height (<i>xxx.x</i>)	150.1 cm
Weight (<i>xxx.x</i>)	83.0 kg
BMI (<i>xxx.x</i>)	36.83975 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:42:07

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Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 17 Feb 2021 13:42:06

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Date of assessment (dd MMM yyyy) 19 OCT 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☒
Post-menopausal ☐
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1998

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:42:07

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☒ No ☐

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:42:07

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	19 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

What was the date of randomization? (dd MMM yyyy) 19 OCT 2020

What was the participant's randomization number? 117421

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 12:50
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	15:52 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 15:52
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 19 OCT 2020

What was the treatment time? (00:00-23:59) 15:22 (24 HR)

Treatment Date and Time (derived) 19 OCT 2020 15:22

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	19 OCT 2020
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Collection time (00:00-23:59)	14:13 (24 HR)
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Collection date and time (derived)	19 OCT 2020 14:13
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US3172406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Collection date (dd MMM yyyy)			19 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:16	19 OCT 2020 14:16
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐
No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp 19 OCT 2020 15:55

PC Open Date & Time 19 OCT 2020 15:42

PC Close Date & Time 19 OCT 2020 18:12

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☒ No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred True

To **PREVENT** pain or fever from occurring False

PC Time Stamp 20 OCT 2020 00:55

PC Open Date & Time 19 OCT 2020 19:07

PC Close Date & Time 20 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

20 OCT 2020 21:35

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

21 OCT 2020 12:01

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

22 OCT 2020 12:01

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

23 OCT 2020 17:01

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

24 OCT 2020 19:42

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

25 OCT 2020 19:05

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 OCT 2020 15:55

PC Open Date & Time

19 OCT 2020 15:42

PC Close Date & Time

19 OCT 2020 18:12

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☒

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 00:56

PC Open Date & Time

19 OCT 2020 19:07

PC Close Date & Time

20 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☒

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

100

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 OCT 2020 21:37

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 OCT 2020 12:02

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 12:01

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 OCT 2020 17:01

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 OCT 2020 19:43

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 OCT 2020 19:06

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	19 OCT 2020 15:55
PC Open Date & Time	19 OCT 2020 15:42
PC Close Date & Time	19 OCT 2020 18:12

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	20 OCT 2020 00:57
PC Open Date & Time	19 OCT 2020 19:07
PC Close Date & Time	20 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

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EAB) (1725)

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 21:38
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

55 of 1854

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 12:02
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☒

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 12:02
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

59 of 1854

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 17:02
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 19:43
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

63 of 1854

EAB) (1725)

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 19:06
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3172406

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 27 OCT 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3172406

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172406

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3172406

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172406

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 09 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3172406

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172406

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	16 NOV 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	12:18 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 12:18
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	16:55 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 16:55
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3172406

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3172406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 16 NOV 2020

What was the treatment time? (00:00-23:59) 16:25 (24 HR)

Treatment Date and Time (derived) 16 NOV 2020 16:25

Which arm was used to give treatment? Left Arm ☒
Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3172406

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	16 NOV 2020
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Collection time (00:00-23:59)	13:00 (24 HR)
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Collection date and time (derived)	16 NOV 2020 13:00
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US3172406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Collection date (dd MMM yyyy)			16 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:03	16 NOV 2020 13:03
Nasopharyngeal Swab 2	No		

US3172406

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

16 NOV 2020 16:56

PC Open Date & Time

16 NOV 2020 16:45

PC Close Date & Time

16 NOV 2020 19:15

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☒ No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred True

To **PREVENT** pain or fever from occurring False

PC Time Stamp 17 NOV 2020 00:17

PC Open Date & Time 16 NOV 2020 20:10

PC Close Date & Time 17 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 99.6 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☒ No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred True

To **PREVENT** pain or fever from occurring False

PC Time Stamp 18 NOV 2020 00:00

PC Open Date & Time 17 NOV 2020 12:00

PC Close Date & Time 18 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

19 NOV 2020 00:00

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

19 NOV 2020 23:59

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

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If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☒

No ☐

Please confirm reason for pain or fever medication (may select more than one):

To **TREAT** pain or fever that has already occurred

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

20 NOV 2020 22:17

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

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If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

21 NOV 2020 23:59

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

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Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

23 NOV 2020 00:38

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 NOV 2020 16:56

PC Open Date & Time

16 NOV 2020 16:45

PC Close Date & Time

16 NOV 2020 19:15

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☒

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 NOV 2020 00:18

PC Open Date & Time

16 NOV 2020 20:10

PC Close Date & Time

17 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☒

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☒

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

100

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 NOV 2020 00:01

PC Open Date & Time

17 NOV 2020 12:00

PC Close Date & Time

18 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 NOV 2020 00:01

PC Open Date & Time

18 NOV 2020 12:00

PC Close Date & Time

19 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 NOV 2020 00:00

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 NOV 2020 22:16

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 NOV 2020 00:00

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☐

Please select one response below

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 NOV 2020 00:39

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	16 NOV 2020 16:57
PC Open Date & Time	16 NOV 2020 16:45
PC Close Date & Time	16 NOV 2020 19:15

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

- None ☐
- No interference with activity ☒
- Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐
- Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

- None ☐
- No interference with activity ☐
- Some interference with activity ☒
- Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

- None ☐
- No interference with activity ☐
- Some interference with activity ☒
- Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

- None ☐
- No interference with activity ☐
- Some interference with activity ☒
- Significant; prevents daily
activity ☐

NAUSEA/VOMITING

- None ☒
- No interference with activity or
1-2 episodes/24 hours ☐
- Some interference with activity
or >2 episodes/24 hours ☐
- Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

- None ☐
- No interference with activity ☒
- Some interference with activity
not requiring medical attention ☐
- Prevents daily activity and
requires medical attention ☐

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

PC Time stamp	17 NOV 2020 00:20
PC Open Date & Time	16 NOV 2020 20:10
PC Close Date & Time	17 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☒

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☒

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☒

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

Yes <input type="checkbox"/>	
PC Time stamp	18 NOV 2020 00:02
PC Open Date & Time	17 NOV 2020 12:00
PC Close Date & Time	18 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☒

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

101 of 1854

EAB) (1725)

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

Yes <input type="checkbox"/>	
PC Time stamp	19 NOV 2020 00:02
PC Open Date & Time	18 NOV 2020 12:00
PC Close Date & Time	19 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☒

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

Yes <input type="checkbox"/>	
PC Time stamp	20 NOV 2020 00:01
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☒

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

Yes <input type="checkbox"/>	
PC Time stamp	20 NOV 2020 22:24
PC Open Date & Time	20 NOV 2020 12:00
PC Close Date & Time	21 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

No interference with activity or
1-2 episodes/24 hours ☒

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

107 of 1854

EAB) (1725)

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

Yes <input type="checkbox"/>	
PC Time stamp	22 NOV 2020 00:02
PC Open Date & Time	21 NOV 2020 12:00
PC Close Date & Time	22 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

Yes <input type="checkbox"/>	
PC Time stamp	23 NOV 2020 00:40
PC Open Date & Time	22 NOV 2020 12:00
PC Close Date & Time	23 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 8

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 23 NOV 2020 23:59

PC Open Date & Time 23 NOV 2020 12:00

PC Close Date & Time 24 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 23 NOV 2020 23:59

PC Open Date & Time 23 NOV 2020 12:00

PC Close Date & Time 24 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 24 NOV 2020 00:00

PC Open Date & Time 23 NOV 2020 12:00

PC Close Date & Time 24 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 24 NOV 2020 00:00

PC Open Date & Time 23 NOV 2020 12:00

PC Close Date & Time 24 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time 23 NOV 2020 12:00

PC Close Date & Time 24 NOV 2020 11:59

PC Time stamp 24 NOV 2020 00:00

US3172406

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	24 NOV 2020 00:00
PC Open Date & Time	23 NOV 2020 12:00
PC Close Date & Time	24 NOV 2020 11:59

US3172406

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 8

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 24 NOV 2020 00:01

PC Open Date and Time 23 NOV 2020 12:00

PC Close Date and Time 24 NOV 2020 11:59

US3172406

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3172406

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172406

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3172406

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172406

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3172406

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172406

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	14 DEC 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 DEC 2020
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	14 DEC 2020 11:48
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172406

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3172406

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	14 DEC 2020
-------------------------------	-------------

Collection time (00:00-23:59)	12:27 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	14 DEC 2020 12:27
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US3172406

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:42:07

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 61

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

16 DEC 2020 00:23:45

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 01:36:44
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 75

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

30 DEC 2020 09:23:37

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 82

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

06 JAN 2021 02:08:27

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 89

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

13 JAN 2021 20:15:16

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 00:01:57
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

27 JAN 2021 00:01:33

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 110

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

03 FEB 2021 00:01:31

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 117

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

10 FEB 2021 01:11:36

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 17:23:59
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 FEB 2021 05:04:20

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

03 MAR 2021 00:31:47

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 145

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

10 MAR 2021 01:11:39

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 152

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

17 MAR 2021 00:22:22

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 159

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 MAR 2021 00:02:33

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 APR 2021 18:35:16
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

07 APR 2021 17:17:26

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 180

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

14 APR 2021 00:04:53

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 187

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

21 APR 2021 01:59:13

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 17:59:45
Patient Cloud Open Date & Time	28 APR 2021 00:01
Patient Cloud Close Date & Time	02 MAY 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 250

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 257

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 278

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 285

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 292

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 299

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 313

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 AUG 2021 00:01
Patient Cloud Close Date & Time	29 AUG 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 334

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	15 SEP 2021 00:01
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Patient Cloud Close Date & Time	19 SEP 2021 23:59
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US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 348

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 376

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 390

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 418

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 432

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 439

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 DEC 2021 00:01
Patient Cloud Close Date & Time	02 JAN 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 488

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 495

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 516

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

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27 MAR 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 530

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 544

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	20 APR 2022 00:01
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Patient Cloud Close Date & Time	24 APR 2022 23:59
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US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 565

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 628

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 635

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 656

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	10 AUG 2022 00:01
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Patient Cloud Close Date & Time	14 AUG 2022 23:59
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US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 670

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 691

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 705

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 712

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 719

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	05 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 726

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

Patient Cloud Open Date & Time	26 OCT 2022 00:01
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Patient Cloud Close Date & Time	30 OCT 2022 23:59
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US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

[Patient Cloud Open Date & Time](#)

09 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 761

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	16 NOV 2022 00:01
Patient Cloud Close Date & Time	20 NOV 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

27 NOV 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

04 DEC 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	07 DEC 2022 00:01
Patient Cloud Close Date & Time	11 DEC 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
Patient Cloud Open Date & Time	14 DEC 2022 00:01
Patient Cloud Close Date & Time	18 DEC 2022 23:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

DAY 796

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

25 DEC 2022 23:59

US3172406

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:31:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 01:27:21

US3172406

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 JAN 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3172406

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172406

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 14:44:51

Generated On: 09 Jun 2021 15:31:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 FEB 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3172406

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 14:44:51

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172406

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3172406

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172406

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3172406

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172406

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:31:26

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3172406

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:31:26

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Mar 2021 14:44:51

Generated On: 09 Jun 2021 15:31:26

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 04 MAR 2021

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☒

Folder OID UNBLND_DECIDE

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

Date of updated informed consent (dd MMM yyyy) 06 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 04 MAR 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Mar 2021 14:44:51

Generated On: 09 Jun 2021 15:31:26

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	04 MAR 2021
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Collection time (00:00-23:59)	16:12 (24 HR)
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Collection date and time (derived)	04 MAR 2021 16:12
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US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Mar 2021 14:44:51

Generated On: 09 Jun 2021 15:31:26

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 MAR 2021

Collection time (00:00 - 23:59)

16:13

Collection Date and Time (derived)

04 MAR 2021 16:13

US3172406

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

AEID	USA-US118-2021-MRNA-1273-P30 1000007
Adverse event	LEFT KNEE PATELLA FRACTURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	31 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	09 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	12 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	337 of 1854

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	LEFT KNEE PATELLA FRACTURE SECONDARY TO FALL ON 31JAN2021 REQUIRING SURGICAL RPAIE AND 3 DAYS HOSPILIZATION. WILL START REHAB IN 6 WEEKS. WILL REQUEST RECORDS FOR DETAILS.
Serious Adverse Event Derived (CSA Programming Field Only)	1

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication LEFT ARM PAIN AT INJECTION
SITE (SOLICITED ADVERSE
REACTION) (NOT AN A/E)

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE, CHILLS, BODY
ACHE, MYALGIA,
ARTHRALGIA, INJECTION SITE
PAIN (SOLICITED ADVERSE
REACTION) (NOT AN A/E)

Dose per administration 500

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐

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EAB) (1725)

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US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	18 NOV 2020	
Was this medication taken for solicited event?	Yes <input checked="" type="checkbox"/>	
	No <input type="checkbox"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

Name of Medication TEKTURNA

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 300/25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

Name of Medication METROPOLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 5000

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify UNITS

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☒
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

Name of Medication TYLENOL (ACETAMINOPHEN
300MG / CODEINE 30 MG)

Prophylaxis Yes ☐
No ☒

Indication LEFT KNEE FRACTURE - SAE

Dose per administration 330

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	09 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication LEFT KNEE PAIN SECONDARY
TO FRACTURE - SAE

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

TID / PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 16:41:41

Generated On: 09 Jun 2021 15:31:26

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	31 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		08 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3172406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Feb 2021 13:42:06

Generated On: 09 Jun 2021 15:31:26

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3172406

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:31:26

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3172406

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:31:26

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 03 Mar 2021 14:02:34

Generated On: 09 Jun 2021 15:31:26

SAEID	USA-US118-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 03 Mar 2021 14:02:34

Generated On: 09 Jun 2021 15:31:26

SAEID	USA-US118-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	17/FEB/2021 10:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 03 Mar 2021 14:02:34

Generated On: 09 Jun 2021 15:31:26

SAEID	USA-US118-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	26/FEB/2021 11:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3172406 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172406

Form: Participant Creation

Generated On: 09 Jun 2021 15:31:26

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'US3172406'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Oct 2020 16:43:34

US3172406

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:01:27

US3172406

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '19 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Oct 2020 16:43:35

US3172406

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4)	19 Oct 2020 21:01:27
	(b) (4)	

US3172406

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'SCRN'	System	19 Oct 2020 21:01:27

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered (b) (6) 1960'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Oct 2020 16:43:36

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '60'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:02:16

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'YEARS'	System	19 Oct 2020 21:02:16

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '60'	System	19 Oct 2020 19:34:49

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Female (F)'	Mariete Rendon (b) (4)	19 Oct 2020 21:02:16
	(b) (4)	

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4)	19 Oct 2020 21:02:16
	(b) (4)	

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'I'	Mariete Rendon (b) (4)	19 Oct 2020 21:02:16
	(b) (4)	

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Oct 2020 21:02:16
	(b) (4)	

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:02:16

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Oct 2020 21:02:16
	(b) (4)	

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Oct 2020 21:02:16
	(b) (4)	

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Oct 2020 21:02:16
	(b) (4)	

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Oct 2020 21:02:16
	(b) (4)	

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Oct 2020 21:02:16
	(b) (4)	

US3172406

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:26

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:02:16

US3172406

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:26

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '19 Oct 2020'	Mariete Rendon (b) (4)	19 Oct 2020 19:34:49
	(b) (4)	

US3172406

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:26

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Oct 2020'	System	19 Oct 2020 19:34:49

US3172406

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:26

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '2020'	System	19 Oct 2020 19:34:49

US3172406

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:26

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Amendment 3 (3)'	Mariete Rendon (b) (4)	19 Oct 2020 19:34:49
	(b) (4)	

US3172406

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:26

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 19:34:49

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Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:26

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Oct 2020 19:34:49
	(b) (4)	

US3172406

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:26

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Oct 2020 19:34:49
	(b) (4)	

US3172406

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:26

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Oct 2020 19:34:49
	(b) (4)	

US3172406

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:26

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Oct 2020 16:43:35

US3172406

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:26

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'I'	System	19 Oct 2020 19:34:52

US3172406

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:31:26

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 19:34:52

US3172406

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:31:26

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:26

US3172406

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 21:05:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 21:05:22
	(b) (4)	
Data point term sent to Coder	System	19 Oct 2020 21:04:06
User entered 'PRESBYOPIA'	Mariete Rendon (b) (4)	19 Oct 2020 21:03:40
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 2000'	Mariete Rendon (b) (4)	19 Oct 2020 21:03:40
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:40

US3172406

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:40

US3172406

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Oct 2020 21:03:40
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Oct 2020 21:03:40
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 2000'	System	19 Oct 2020 21:03:40

US3172406

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '2000'	System	19 Oct 2020 21:03:40

US3172406

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	19 Oct 2020 21:03:40

US3172406

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	19 Oct 2020 21:03:40

US3172406

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Bleeding menstrual heavy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 06:38:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 06:38:41
Data point term sent to Coder	System	20 Oct 2020 18:52:28
User entered 'HEAVY MENSTRUAL BLEEDING (RELATED TO UTERINE FIBROIDS)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:52:08

US3172406

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 1998'	Mariete Rendon (b) (4)	20 Oct 2020 18:52:08
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 18:52:08
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	20 Oct 2020 18:52:08
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 1998'	Mariete Rendon (b) (4)	20 Oct 2020 18:52:08
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 18:52:08
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 1998'	System	20 Oct 2020 18:52:08

US3172406

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '1998'	System	20 Oct 2020 18:52:08

US3172406

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 1998'	System	20 Oct 2020 18:52:08

US3172406

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '1998'	System	20 Oct 2020 18:52:08

US3172406

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 04:25:53
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:27:13
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 02:29:57
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:53:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:53:46
Data point term sent to Coder	System	20 Oct 2020 18:52:28
User entered 'HYPERTENSION'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:52:22

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 2000'	Mariete Rendon (b) (4)	20 Oct 2020 18:52:22
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:52:22

US3172406

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	20 Oct 2020 18:52:22
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 18:52:22
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 18:52:22
	(b) (4)	

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 2000'	System	20 Oct 2020 18:52:22

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '2000'	System	20 Oct 2020 18:52:22

US3172406

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	20 Oct 2020 18:52:22

US3172406

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	20 Oct 2020 18:52:22

US3172406

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Gastritis (excl infective), PT: Chronic gastritis, LLT: Chronic gastritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:53:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:53:46
Data point term sent to Coder	System	20 Oct 2020 18:53:30
User entered 'CHRONIC GASTRITIS'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:52:51

US3172406

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 2010'	Mariete Rendon (b) (4)	20 Oct 2020 18:52:51
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 18:52:51
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	20 Oct 2020 18:52:51
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 18:52:51
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 18:52:51
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 2010'	System	20 Oct 2020 18:52:51

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '2010'	System	20 Oct 2020 18:52:51

US3172406

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	20 Oct 2020 18:52:51

US3172406

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	20 Oct 2020 18:52:51

US3172406

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:53:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:53:47
Data point term sent to Coder	System	20 Oct 2020 18:53:31
User entered 'OBESE'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:53:09

US3172406

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 2000'	Mariete Rendon (b) (4)	20 Oct 2020 18:53:09
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:53:09

US3172406

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	20 Oct 2020 18:53:09
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 18:53:09
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 18:53:09
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 2000'	System	20 Oct 2020 18:53:09

US3172406

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '2000'	System	20 Oct 2020 18:53:09

US3172406

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	20 Oct 2020 18:53:09

US3172406

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	20 Oct 2020 18:53:09

US3172406

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:55:41
Data point term sent to Coder	System	20 Oct 2020 18:54:31
User entered 'UTERINE FIBROIDS'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:53:38

US3172406

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'UN UNK 1998'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:53:38

US3172406

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:53:38

US3172406

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	20 Oct 2020 18:53:38
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 1998'	Mariete Rendon (b) (4)	20 Oct 2020 18:53:38
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 18:53:38
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 1998'	System	20 Oct 2020 18:53:38

US3172406

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '1998'	System	20 Oct 2020 18:53:38

US3172406

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 1998'	System	20 Oct 2020 18:53:38

US3172406

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '1998'	System	20 Oct 2020 18:53:38

US3172406

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalized osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:55:41
Data point term sent to Coder	System	20 Oct 2020 18:54:33
User entered 'GENERALIZED OSTEOARTHRITIS'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:54:10

US3172406

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 2010'	Mariete Rendon (b) (4)	20 Oct 2020 18:54:10
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 18:54:10
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:54:10

US3172406

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 18:54:10
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 18:54:10
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 2010'	System	20 Oct 2020 18:54:10

US3172406

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '2010'	System	20 Oct 2020 18:54:10

US3172406

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	20 Oct 2020 18:54:10

US3172406

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	20 Oct 2020 18:54:10

US3172406

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:26

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Foot fracture, LLT: Fractured toe - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:48:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:48:33
Data point term sent to Coder	System	20 Oct 2020 18:55:34
User entered 'RIGHT SECOND TOE FRACTURE'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:54:50

US3172406

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 2000'	Mariete Rendon (b) (4)	20 Oct 2020 18:54:50
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 18:54:50
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:54:50

US3172406

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:26

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 2000'	Mariete Rendon (b) (4)	20 Oct 2020 18:54:50
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 18:54:50
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 2000'	System	20 Oct 2020 18:54:50

US3172406

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '2000'	System	20 Oct 2020 18:54:50

US3172406

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 2000'	System	20 Oct 2020 18:54:50

US3172406

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '2000'	System	20 Oct 2020 18:54:50

US3172406

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 09:40:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 09:40:33
Data point term sent to Coder	System	20 Oct 2020 18:56:35
User entered 'ASPIRIN ALLERGY (HYPOTENSION) (NO ANAPHALAXIS)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:55:42

US3172406

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'UN UNK 2010' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:03:34
User closed query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	20 Oct 2020 22:02:27
User entered 'UN UNK 2015' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:02:27
User opened query 'Start date is missing and Start date is completely unknown has not been checked. Please correct.' (Site from System).	System	20 Oct 2020 18:55:42
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:55:42

US3172406

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:55:42

US3172406

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	20 Oct 2020 18:55:42
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 18:55:42
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:55:42

US3172406

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 2010'	System	20 Oct 2020 22:03:34
User entered 'Jan 2015'	System	20 Oct 2020 22:02:27
User entered empty.	System	20 Oct 2020 18:55:42

US3172406

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '2010'	System	20 Oct 2020 22:03:34
User entered '2015'	System	20 Oct 2020 22:02:27
User entered empty.	System	20 Oct 2020 18:55:42

US3172406

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	20 Oct 2020 18:55:42

US3172406

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	20 Oct 2020 18:55:42

US3172406

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Subtotal hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:57:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:57:41
Data point term sent to Coder	System	20 Oct 2020 18:56:35
User entered 'PARTIAL HYSTERECTOMY'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:56:10

US3172406

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'UN UNK 1998'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:56:10

US3172406

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:56:10

US3172406

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	20 Oct 2020 18:56:10
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 1998'	Mariete Rendon (b) (4)	20 Oct 2020 18:56:10
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 18:56:10
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 1998'	System	20 Oct 2020 18:56:10

US3172406

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '1998'	System	20 Oct 2020 18:56:10

US3172406

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 1998'	System	20 Oct 2020 18:56:10

US3172406

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '1998'	System	20 Oct 2020 18:56:10

US3172406

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:26

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Fracture treatments (excl skull and spine), PT: Fracture treatment, LLT: Fracture repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 10:42:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 10:42:03
Data point term sent to Coder	System	20 Oct 2020 18:57:37
User entered 'RIGHT 2ND TOE FRACTURE SURGERY'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:56:55

US3172406

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:26

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'UN UNK 2000'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:56:55

US3172406

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:56:55

US3172406

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:26

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	20 Oct 2020 18:56:55
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:26

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 2000'	Mariete Rendon (b) (4)	20 Oct 2020 18:56:55
	(b) (4)	

US3172406

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:26

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 18:56:55

US3172406

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:26

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 2000'	System	20 Oct 2020 18:56:55

US3172406

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:26

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '2000'	System	20 Oct 2020 18:56:55

US3172406

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:26

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'Jan 2000'	System	20 Oct 2020 18:56:55

US3172406

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:26

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '2000'	System	20 Oct 2020 18:56:55

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:02:57

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '19 Oct 2020'	Mariete Rendon (b) (4)	19 Oct 2020 21:02:57
	(b) (4)	

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '12:50'	Mariete Rendon (b) (4)	19 Oct 2020 21:02:57
	(b) (4)	

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '19 Oct 2020 12:50'	System	19 Oct 2020 21:02:57

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '150.1' cm	Mariete Rendon (b) (4)	19 Oct 2020 21:02:57
	(b) (4)	
DataPoint set to visible.	System	19 Oct 2020 19:34:52

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '83.0' kg	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:02:57
DataPoint set to visible.	System	19 Oct 2020 19:34:52

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '36.83975'	System	19 Oct 2020 21:02:57
DataPoint set to visible.	System	19 Oct 2020 19:34:52

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'kg/m2'	System	19 Oct 2020 21:02:57
DataPoint set to visible.	System	19 Oct 2020 19:34:52

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	19 Oct 2020 21:02:57
	(b) (4)	

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:02:57

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Oct 2020 21:02:57
	(b) (4)	

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	19 Oct 2020 21:02:57
	(b) (4)	

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'bpm'	System	19 Oct 2020 21:02:57

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:02:57

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'breaths/min'	System	19 Oct 2020 21:02:57

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:02:57

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'mmHg'	System	19 Oct 2020 21:02:57

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:02:57

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'mmHg'	System	19 Oct 2020 21:02:57

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20

US3172406

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20

US3172406

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:04

US3172406

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Oct 2020 21:03:04
	(b) (4)	

US3172406

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '19 Oct 2020'	Mariete Rendon (b) (4)	19 Oct 2020 21:03:16
	(b) (4)	

US3172406

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:26

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:16

US3172406

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:26

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Surgically sterile (SURGICALLY STERILE)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:16

US3172406

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:26

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:16

US3172406

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:26

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'UN UNK 1998'	Mariete Rendon (b) (4)	19 Oct 2020 21:03:16
	(b) (4)	

US3172406

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:26

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Oct 2020 21:03:16
	(b) (4)	

US3172406

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:26

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Oct 2020 21:03:16
	(b) (4)	

US3172406

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:31:26

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:16

US3172406

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:26

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	19 Oct 2020 21:01:53
	(b) (4)	

US3172406

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:26

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Oct 2020 21:01:53
	(b) (4)	

US3172406

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:26

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:01:53

US3172406

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:26

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:01:53

US3172406

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:26

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Oct 2020 21:01:53
	(b) (4)	

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Folder: Screening

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Oct 2020 21:01:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Oct 2020 21:01:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:01:53

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Folder: Screening

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Oct 2020 21:01:53
	(b) (4)	

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Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Oct 2020 21:01:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Oct 2020 21:01:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:26

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Oct 2020 21:01:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Oct 2020 21:01:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:01:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:26

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Oct 2020 21:01:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:26

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:01:53

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:49

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '19 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:49

US3172406

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4)	19 Oct 2020 21:03:49
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'VISIT1'	System	19 Oct 2020 21:03:49

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:26

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '19 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Oct 2020 17:53:28

US3172406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:26

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '117421'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Oct 2020 17:53:28

US3172406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:26

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Oct 2020 17:53:28

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:26

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:56

US3172406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:26

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:56

US3172406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:26

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:56

US3172406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:26

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:56

US3172406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:26

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:56

US3172406

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:26

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:03:56
DataPoint set to visible.	System	19 Oct 2020 19:34:49

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '19 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '12:50'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '19 Oct 2020 12:50'	System	19 Oct 2020 21:04:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '36.8' C	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '76'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'bpm'	System	19 Oct 2020 21:04:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '17'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'breaths/min'	System	19 Oct 2020 21:04:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '125'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'mmHg'	System	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '86'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'mmHg'	System	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:26

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:26

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '19 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '15:52'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '19 Oct 2020 15:52'	System	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '36.9' C	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '73'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'bpm'	System	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '16'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'breaths/min'	System	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '147'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'mmHg'	System	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '84'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'mmHg'	System	19 Oct 2020 21:04:59

US3172406

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:05

US3172406

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:26

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '19 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:05

US3172406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 19:35:41

US3172406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 19:35:41

US3172406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	19 Oct 2020 19:35:41
	(b) (4)	

US3172406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'MRNA-1273 OR PLACEBO'	System	19 Oct 2020 19:35:41

US3172406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '19 Oct 2020'	Mariete Rendon (b) (4)	19 Oct 2020 19:35:41
	(b) (4)	

US3172406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '15:22'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 19:35:41

US3172406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '19 Oct 2020 15:22'	System	19 Oct 2020 19:35:41

US3172406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Left Arm (LEFT ARM)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 19:35:41

US3172406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'ONCE'	System	19 Oct 2020 19:35:41

US3172406

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'INTRAMUSCULAR'	System	19 Oct 2020 19:35:41

US3172406

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:41

US3172406

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '19 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:41

US3172406

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '14:13'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:41

US3172406

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '19 Oct 2020 14:13'	System	19 Oct 2020 21:05:41

US3172406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:31:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '19 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:50

US3172406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:50

US3172406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:50

US3172406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '14:16'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:50

US3172406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '19 Oct 2020 14:16'	System	19 Oct 2020 21:05:50

US3172406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:50

US3172406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:50

US3172406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:50

US3172406

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered empty.	System	19 Oct 2020 21:05:50

US3172406

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	29 Oct 2020 18:53:19
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:54:42
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:05:55

US3172406

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '1'	System	29 Oct 2020 18:53:19
User entered empty.	System	21 Oct 2020 20:54:42
User entered '1'	System	19 Oct 2020 21:05:55

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:54:35', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '3e6ab4a6-b20e-4ff2-9c9d-8e08b8eb6104' User entered 'Yes (Y)'	System	19 Oct 2020 19:55:04
	System	19 Oct 2020 19:55:04

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:54:52', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '3e6ab4a6-b20e-4ff2-9c9d-8e08b8eb6104' User entered '98.4'	System	19 Oct 2020 19:55:04
	System	19 Oct 2020 19:55:04

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:54:59', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '3e6ab4a6-b20e-4ff2-9c9d-8e08b8eb6104' User entered 'No (N)'	System	19 Oct 2020 19:55:04
	System	19 Oct 2020 19:55:04

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '3e6ab4a6-b20e-4ff2-9c9d-8e08b8eb6104'	System	19 Oct 2020 19:55:04
User entered '19 Oct 2020 15:55'	System	19 Oct 2020 19:55:04

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Oct 2020 15:42'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Oct 2020 18:12'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:54:04', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b388f9a3-de68-4c66-82f9-f34c102f0989' User entered 'Yes (Y)'	System	20 Oct 2020 04:55:12
	System	20 Oct 2020 04:55:12

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:54:15', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b388f9a3-de68-4c66-82f9-f34c102f0989' User entered '98.0'	System	20 Oct 2020 04:55:12
	System	20 Oct 2020 04:55:12

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:54:24', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b388f9a3-de68-4c66-82f9-f34c102f0989' User entered 'Yes (Y)'	System	20 Oct 2020 04:55:12
	System	20 Oct 2020 04:55:12

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated in conmed log' (Site from System).	(b) (4), (b) (6)	26 Oct 2020 15:58:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Mariete Rendon (b) (4)	20 Oct 2020 22:02:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:54:59', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b388f9a3-de68-4c66-82f9-f34c102f0989'	(b) (4)	
User entered '1'	System	20 Oct 2020 04:55:12
	System	20 Oct 2020 04:55:12
	System	20 Oct 2020 04:55:12

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:54:59', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b388f9a3-de68-4c66-82f9-f34c102f0989' User entered '0'	System	20 Oct 2020 04:55:12
	System	20 Oct 2020 04:55:12

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:55:09', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b388f9a3-de68-4c66-82f9-f34c102f0989' User entered '20 Oct 2020 00:55'	System	20 Oct 2020 04:55:12
	System	20 Oct 2020 04:55:12

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Oct 2020 19:07'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 2'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:34:39', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a27879a2-e758-4a80-9dd9-e206403566d7' User entered 'Yes (Y)'	System	21 Oct 2020 01:35:21
	System	21 Oct 2020 01:35:21

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:34:50', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a27879a2-e758-4a80-9dd9-e206403566d7' User entered '97.8'	System	21 Oct 2020 01:35:21
	System	21 Oct 2020 01:35:21

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:34:56', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a27879a2-e758-4a80-9dd9-e206403566d7'	System	21 Oct 2020 01:35:21
User entered 'No (N)'	System	21 Oct 2020 01:35:21

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:35:16', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a27879a2-e758-4a80-9dd9-e206403566d7' User entered '20 Oct 2020 21:35'	System	21 Oct 2020 01:35:21
	System	21 Oct 2020 01:35:21

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 3'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:01:07', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '563ca249-ad35-4ccc-860e-2ac4d74d2395' User entered 'Yes (Y)'	System	21 Oct 2020 16:02:21
	System	21 Oct 2020 16:02:21

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:01:16', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '563ca249-ad35-4ccc-860e-2ac4d74d2395' User entered '97.6'	System	21 Oct 2020 16:02:21
	System	21 Oct 2020 16:02:21

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:01:21', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '563ca249-ad35-4ccc-860e-2ac4d74d2395'	System	21 Oct 2020 16:02:21
User entered 'No (N)'	System	21 Oct 2020 16:02:21

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:01:35', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '563ca249-ad35-4ccc-860e-2ac4d74d2395' User entered '21 Oct 2020 12:01'	System	21 Oct 2020 16:02:21
	System	21 Oct 2020 16:02:21

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 4'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:00:45', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '23dda367-ce89-46dd-a026-111b8817f992'	System	22 Oct 2020 16:01:38
User entered 'Yes (Y)'	System	22 Oct 2020 16:01:38

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:00:51', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '23dda367-ce89-46dd-a026-111b8817f992' User entered '97.8'	System	22 Oct 2020 16:01:38
	System	22 Oct 2020 16:01:38

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:00:55', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '23dda367-ce89-46dd-a026-111b8817f992'	System	22 Oct 2020 16:01:38
User entered 'No (N)'	System	22 Oct 2020 16:01:38

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:01:03', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '23dda367-ce89-46dd-a026-111b8817f992' User entered '22 Oct 2020 12:01'	System	22 Oct 2020 16:01:38
	System	22 Oct 2020 16:01:38

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 5'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:00:45', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '6eab0d7b-6ac8-46d5-a6f8-4f0f4dc86db1' User entered 'Yes (Y)'	System	23 Oct 2020 21:01:07
	System	23 Oct 2020 21:01:07

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:00:51', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '6eab0d7b-6ac8-46d5-a6f8-4f0f4dc86db1' User entered '98.0'	System	23 Oct 2020 21:01:07
	System	23 Oct 2020 21:01:07

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:00:55', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '6eab0d7b-6ac8-46d5-a6f8-4f0f4dc86db1' User entered 'No (N)'	System	23 Oct 2020 21:01:07
	System	23 Oct 2020 21:01:07

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:01:01', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '6eab0d7b-6ac8-46d5-a6f8-4f0f4dc86db1' User entered '23 Oct 2020 17:01'	System	23 Oct 2020 21:01:07
	System	23 Oct 2020 21:01:07

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 6'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:42:41', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '41f6b872-ca89-4b84-b182-056019756ba4' User entered 'Yes (Y)'	System	24 Oct 2020 23:43:02
	System	24 Oct 2020 23:43:02

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:42:48', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '41f6b872-ca89-4b84-b182-056019756ba4' User entered '97.6'	System	24 Oct 2020 23:43:02
	System	24 Oct 2020 23:43:02

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:42:52', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '41f6b872-ca89-4b84-b182-056019756ba4' User entered 'No (N)'	System	24 Oct 2020 23:43:02
	System	24 Oct 2020 23:43:02

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:42:57', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '41f6b872-ca89-4b84-b182-056019756ba4' User entered '24 Oct 2020 19:42'	System	24 Oct 2020 23:43:02
	System	24 Oct 2020 23:43:02

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 7'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:04:57', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'df5a5345-4fd8-4474-925f-14d07a18eb3e' User entered 'Yes (Y)'	System	25 Oct 2020 23:05:21
	System	25 Oct 2020 23:05:21

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:05:05', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'df5a5345-4fd8-4474-925f-14d07a18eb3e' User entered '97.6'	System	25 Oct 2020 23:05:21
	System	25 Oct 2020 23:05:21

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:05:08', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'df5a5345-4fd8-4474-925f-14d07a18eb3e' User entered 'No (N)'	System	25 Oct 2020 23:05:21
	System	25 Oct 2020 23:05:21

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:05:13', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'df5a5345-4fd8-4474-925f-14d07a18eb3e' User entered '25 Oct 2020 19:05'	System	25 Oct 2020 23:05:21
	System	25 Oct 2020 23:05:21

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:08', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '96564350-f002-4eb6-a2b3-ab57d82ee816' User entered 'None (1)'	System	19 Oct 2020 19:55:48
	System	19 Oct 2020 19:55:48

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:21', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '96564350-f002-4eb6-a2b3-ab57d82ee816' User entered 'No (N)'	System	19 Oct 2020 19:55:48
	System	19 Oct 2020 19:55:48

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:25', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '96564350-f002-4eb6-a2b3-ab57d82ee816' User entered 'No (N)'	System	19 Oct 2020 19:55:48
	System	19 Oct 2020 19:55:48

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:31', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '96564350-f002-4eb6-a2b3-ab57d82ee816'	System	19 Oct 2020 19:55:48
User entered 'None (1)'	System	19 Oct 2020 19:55:48

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:33', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '96564350-f002-4eb6-a2b3-ab57d82ee816' User entered '19 Oct 2020 15:55'	System	19 Oct 2020 19:55:48
	System	19 Oct 2020 19:55:48

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Oct 2020 15:42'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Oct 2020 18:12'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:55:50', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '196b286d-2cf9-4a02-81b1-61bf15237791'	System	20 Oct 2020 04:56:21
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	20 Oct 2020 04:56:21

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:55:54', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '196b286d-2cf9-4a02-81b1-61bf15237791' User entered 'No (N)'	System	20 Oct 2020 04:56:21
	System	20 Oct 2020 04:56:21

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:56:01', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '196b286d-2cf9-4a02-81b1-61bf15237791' User entered 'No (N)'	System	20 Oct 2020 04:56:21
	System	20 Oct 2020 04:56:21

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:56:13', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '196b286d-2cf9-4a02-81b1-61bf15237791' User entered 'None (1)'	System	20 Oct 2020 04:56:21
	System	20 Oct 2020 04:56:21

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:56:19', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '196b286d-2cf9-4a02-81b1-61bf15237791' User entered '20 Oct 2020 00:56'	System	20 Oct 2020 04:56:21
	System	20 Oct 2020 04:56:21

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Oct 2020 19:07'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 2'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:35:40', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2d8757f5-7ecb-418c-a601-84ff5055bc7a'	System	21 Oct 2020 01:37:18
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	21 Oct 2020 01:37:18

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:35:45', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2d8757f5-7ecb-418c-a601-84ff5055bc7a' User entered 'No (N)'	System	21 Oct 2020 01:37:18
	System	21 Oct 2020 01:37:18

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:35:53', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2d8757f5-7ecb-418c-a601-84ff5055bc7a' User entered 'Yes (Y)'	System	21 Oct 2020 01:37:18
	System	21 Oct 2020 01:37:18

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:36:37', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2d8757f5-7ecb-418c-a601-84ff5055bc7a' User entered '100'	System	21 Oct 2020 01:37:18
	System	21 Oct 2020 01:37:18

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:36:58', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2d8757f5-7ecb-418c-a601-84ff5055bc7a' User entered 'None (1)'	System	21 Oct 2020 01:37:18
	System	21 Oct 2020 01:37:18

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:37:17', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2d8757f5-7ecb-418c-a601-84ff5055bc7a' User entered '20 Oct 2020 21:37'	System	21 Oct 2020 01:37:18
	System	21 Oct 2020 01:37:18

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 3'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:01:51', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'fb3aae62-cf3a-4689-a68a-7b3cc8ed9f72'	System	21 Oct 2020 16:02:59
User entered 'Does not interfere with activity (2)'	System	21 Oct 2020 16:02:59

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:01:55', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'fb3aae62-cf3a-4689-a68a-7b3cc8ed9f72'	System	21 Oct 2020 16:02:59
User entered 'No (N)'	System	21 Oct 2020 16:02:59

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:02:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'fb3aae62-cf3a-4689-a68a-7b3cc8ed9f72'	System	21 Oct 2020 16:02:59
User entered 'No (N)'	System	21 Oct 2020 16:02:59

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:02:05', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'fb3aae62-cf3a-4689-a68a-7b3cc8ed9f72'	System	21 Oct 2020 16:02:59
User entered 'None (1)'	System	21 Oct 2020 16:02:59

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:02:12', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'fb3aae62-cf3a-4689-a68a-7b3cc8ed9f72'	System	21 Oct 2020 16:02:59
User entered '21 Oct 2020 12:02'	System	21 Oct 2020 16:02:59

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 4'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:01:16', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'c77da98f-54c0-4ef6-8f66-2491fee0cc41'	System	22 Oct 2020 16:02:20
User entered 'Does not interfere with activity (2)'	System	22 Oct 2020 16:02:20

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:01:21', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'c77da98f-54c0-4ef6-8f66-2491fee0cc41' User entered 'No (N)'	System	22 Oct 2020 16:02:20
	System	22 Oct 2020 16:02:20

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:01:29', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'c77da98f-54c0-4ef6-8f66-2491fee0cc41' User entered 'No (N)'	System	22 Oct 2020 16:02:20
	System	22 Oct 2020 16:02:20

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:01:33', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'c77da98f-54c0-4ef6-8f66-2491fee0cc41' User entered 'None (1)'	System	22 Oct 2020 16:02:20
	System	22 Oct 2020 16:02:20

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:01:38', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'c77da98f-54c0-4ef6-8f66-2491fee0cc41' User entered '22 Oct 2020 12:01'	System	22 Oct 2020 16:02:20
	System	22 Oct 2020 16:02:20

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 5'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:01:07', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '56514cea-0ee7-42a2-abc8-34a7ad7fa42a'	System	23 Oct 2020 21:01:30
User entered 'Does not interfere with activity (2)'	System	23 Oct 2020 21:01:30

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:01:10', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '56514cea-0ee7-42a2-abc8-34a7ad7fa42a' User entered 'No (N)'	System	23 Oct 2020 21:01:30
	System	23 Oct 2020 21:01:30

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:01:14', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '56514cea-0ee7-42a2-abc8-34a7ad7fa42a' User entered 'No (N)'	System	23 Oct 2020 21:01:30
	System	23 Oct 2020 21:01:30

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:01:22', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '56514cea-0ee7-42a2-abc8-34a7ad7fa42a' User entered 'None (1)'	System	23 Oct 2020 21:01:30
	System	23 Oct 2020 21:01:30

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:01:27', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '56514cea-0ee7-42a2-abc8-34a7ad7fa42a' User entered '23 Oct 2020 17:01'	System	23 Oct 2020 21:01:30
	System	23 Oct 2020 21:01:30

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 6'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:02', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bf857346-c7f6-4194-b275-48136db48274' User entered 'None (1)'	System	24 Oct 2020 23:43:28
	System	24 Oct 2020 23:43:28

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:06', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bf857346-c7f6-4194-b275-48136db48274' User entered 'No (N)'	System	24 Oct 2020 23:43:28
	System	24 Oct 2020 23:43:28

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:11', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bf857346-c7f6-4194-b275-48136db48274' User entered 'No (N)'	System	24 Oct 2020 23:43:28
	System	24 Oct 2020 23:43:28

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:21', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bf857346-c7f6-4194-b275-48136db48274' User entered 'None (1)'	System	24 Oct 2020 23:43:28
	System	24 Oct 2020 23:43:28

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:25', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bf857346-c7f6-4194-b275-48136db48274' User entered '24 Oct 2020 19:43'	System	24 Oct 2020 23:43:28
	System	24 Oct 2020 23:43:28

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 7'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:05:22', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7b6f5d84-a28f-42c9-83c5-6af129335c0c'	System	25 Oct 2020 23:06:05
User entered 'None (1)'	System	25 Oct 2020 23:06:05

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:05:25', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7b6f5d84-a28f-42c9-83c5-6af129335c0c' User entered 'No (N)'	System	25 Oct 2020 23:06:05
	System	25 Oct 2020 23:06:05

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:05:53', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7b6f5d84-a28f-42c9-83c5-6af129335c0c' User entered 'No (N)'	System	25 Oct 2020 23:06:05
	System	25 Oct 2020 23:06:05

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:05:56', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7b6f5d84-a28f-42c9-83c5-6af129335c0c'	System	25 Oct 2020 23:06:05
User entered 'None (1)'	System	25 Oct 2020 23:06:05

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:06:01', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7b6f5d84-a28f-42c9-83c5-6af129335c0c' User entered '25 Oct 2020 19:06'	System	25 Oct 2020 23:06:05
	System	25 Oct 2020 23:06:05

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:38', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '26967d0f-6b0f-4693-bd66-02fce024634f' User entered 'None (0)'	System	19 Oct 2020 19:56:02
	System	19 Oct 2020 19:56:02

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:40', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '26967d0f-6b0f-4693-bd66-02fce024634f' User entered 'None (0)'	System	19 Oct 2020 19:56:02
	System	19 Oct 2020 19:56:02

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:44', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '26967d0f-6b0f-4693-bd66-02fce024634f' User entered 'None (0)'	System	19 Oct 2020 19:56:02
	System	19 Oct 2020 19:56:02

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:47', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '26967d0f-6b0f-4693-bd66-02fce024634f' User entered 'None (0)'	System	19 Oct 2020 19:56:02
	System	19 Oct 2020 19:56:02

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:49', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '26967d0f-6b0f-4693-bd66-02fce024634f' User entered 'None (0)'	System	19 Oct 2020 19:56:02
	System	19 Oct 2020 19:56:02

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:51', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '26967d0f-6b0f-4693-bd66-02fce024634f' User entered 'None (0)'	System	19 Oct 2020 19:56:02
	System	19 Oct 2020 19:56:02

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:57', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '26967d0f-6b0f-4693-bd66-02fce024634f' User entered 'No (N)'	System	19 Oct 2020 19:56:02
	System	19 Oct 2020 19:56:02

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-19T15:55:59', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '26967d0f-6b0f-4693-bd66-02fce024634f' User entered '19 Oct 2020 15:55'	System	19 Oct 2020 19:56:02
	System	19 Oct 2020 19:56:02

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Oct 2020 15:42'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Oct 2020 18:12'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 1, after vaccination (at home)'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:56:30', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '148a4ff2-189b-44a9-932d-2637141ac9b0' User entered 'None (0)'	System	20 Oct 2020 04:57:13
	System	20 Oct 2020 04:57:13

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:56:41', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '148a4ff2-189b-44a9-932d-2637141ac9b0'	System	20 Oct 2020 04:57:13
User entered 'Some interference with activity (2)'	System	20 Oct 2020 04:57:13

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:56:46', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '148a4ff2-189b-44a9-932d-2637141ac9b0' User entered 'None (0)'	System	20 Oct 2020 04:57:13
	System	20 Oct 2020 04:57:13

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:56:50', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '148a4ff2-189b-44a9-932d-2637141ac9b0' User entered 'None (0)'	System	20 Oct 2020 04:57:13
	System	20 Oct 2020 04:57:13

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:56:55', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '148a4ff2-189b-44a9-932d-2637141ac9b0' User entered 'None (0)'	System	20 Oct 2020 04:57:13
	System	20 Oct 2020 04:57:13

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:56:59', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '148a4ff2-189b-44a9-932d-2637141ac9b0' User entered 'None (0)'	System	20 Oct 2020 04:57:13
	System	20 Oct 2020 04:57:13

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:57:06', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '148a4ff2-189b-44a9-932d-2637141ac9b0' User entered 'No (N)'	System	20 Oct 2020 04:57:13
	System	20 Oct 2020 04:57:13

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T00:57:11', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '148a4ff2-189b-44a9-932d-2637141ac9b0' User entered '20 Oct 2020 00:57'	System	20 Oct 2020 04:57:13
	System	20 Oct 2020 04:57:13

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Oct 2020 19:07'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '20 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 2'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:37:26', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '30dfc1e3-353b-40e4-922d-891e451b7c58' User entered 'None (0)'	System	21 Oct 2020 01:38:10
	System	21 Oct 2020 01:38:10

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:37:34', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '30dfc1e3-353b-40e4-922d-891e451b7c58'	System	21 Oct 2020 01:38:10
User entered 'Some interference with activity (2)'	System	21 Oct 2020 01:38:10

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:37:41', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '30dfc1e3-353b-40e4-922d-891e451b7c58'	System	21 Oct 2020 01:38:10
User entered 'Some interference with activity (2)'	System	21 Oct 2020 01:38:10

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:37:47', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '30dfc1e3-353b-40e4-922d-891e451b7c58'	System	21 Oct 2020 01:38:10
User entered 'Some interference with activity (2)'	System	21 Oct 2020 01:38:10

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:37:52', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '30dfc1e3-353b-40e4-922d-891e451b7c58' User entered 'None (0)'	System	21 Oct 2020 01:38:10
	System	21 Oct 2020 01:38:10

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:37:55', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '30dfc1e3-353b-40e4-922d-891e451b7c58' User entered 'None (0)'	System	21 Oct 2020 01:38:10
	System	21 Oct 2020 01:38:10

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:37:59', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '30dfc1e3-353b-40e4-922d-891e451b7c58'	System	21 Oct 2020 01:38:10
User entered 'No (N)'	System	21 Oct 2020 01:38:10

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-20T21:38:06', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '30dfc1e3-353b-40e4-922d-891e451b7c58' User entered '20 Oct 2020 21:38'	System	21 Oct 2020 01:38:10
	System	21 Oct 2020 01:38:10

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '20 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '21 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 3'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:02:19', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '0c5d4cf2-5684-4980-8f0a-46553d709bf1' User entered 'None (0)'	System	21 Oct 2020 16:03:38
	System	21 Oct 2020 16:03:38

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:02:27', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '0c5d4cf2-5684-4980-8f0a-46553d709bf1' User entered 'Some interference with activity (2)'	System	21 Oct 2020 16:03:38
	System	21 Oct 2020 16:03:38

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:02:32', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '0c5d4cf2-5684-4980-8f0a-46553d709bf1' User entered 'Some interference with activity (2)'	System	21 Oct 2020 16:03:38
	System	21 Oct 2020 16:03:38

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:02:37', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '0c5d4cf2-5684-4980-8f0a-46553d709bf1' User entered 'None (0)'	System	21 Oct 2020 16:03:38
	System	21 Oct 2020 16:03:38

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:02:40', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '0c5d4cf2-5684-4980-8f0a-46553d709bf1' User entered 'None (0)'	System	21 Oct 2020 16:03:38
	System	21 Oct 2020 16:03:38

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:02:46', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '0c5d4cf2-5684-4980-8f0a-46553d709bf1' User entered 'None (0)'	System	21 Oct 2020 16:03:38
	System	21 Oct 2020 16:03:38

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:02:50', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '0c5d4cf2-5684-4980-8f0a-46553d709bf1' User entered 'No (N)'	System	21 Oct 2020 16:03:38
	System	21 Oct 2020 16:03:38

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-21T12:02:54', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '0c5d4cf2-5684-4980-8f0a-46553d709bf1' User entered '21 Oct 2020 12:02'	System	21 Oct 2020 16:03:38
	System	21 Oct 2020 16:03:38

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '21 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '22 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 4'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:01:50', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7f8c2a06-511c-42d9-834b-2b92f83bc94a'	System	22 Oct 2020 16:03:14
User entered 'No interference with activity (1)'	System	22 Oct 2020 16:03:14

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:01:57', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7f8c2a06-511c-42d9-834b-2b92f83bc94a'	System	22 Oct 2020 16:03:14
User entered 'Some interference with activity (2)'	System	22 Oct 2020 16:03:14

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:02:02', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7f8c2a06-511c-42d9-834b-2b92f83bc94a'	System	22 Oct 2020 16:03:14
User entered 'Some interference with activity (2)'	System	22 Oct 2020 16:03:14

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:02:09', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7f8c2a06-511c-42d9-834b-2b92f83bc94a'	System	22 Oct 2020 16:03:14
User entered 'Some interference with activity (2)'	System	22 Oct 2020 16:03:14

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:02:18', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7f8c2a06-511c-42d9-834b-2b92f83bc94a'	System	22 Oct 2020 16:03:14
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	22 Oct 2020 16:03:14

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:02:27', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7f8c2a06-511c-42d9-834b-2b92f83bc94a' User entered 'None (0)'	System	22 Oct 2020 16:03:14
	System	22 Oct 2020 16:03:14

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:02:30', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7f8c2a06-511c-42d9-834b-2b92f83bc94a' User entered 'No (N)'	System	22 Oct 2020 16:03:14
	System	22 Oct 2020 16:03:14

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-22T12:02:35', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7f8c2a06-511c-42d9-834b-2b92f83bc94a' User entered '22 Oct 2020 12:02'	System	22 Oct 2020 16:03:14
	System	22 Oct 2020 16:03:14

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '22 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 5'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:01:42', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '814d5c7b-3275-4f66-8efa-a0d5317f7a02'	System	23 Oct 2020 21:02:12
User entered 'No interference with activity (1)'	System	23 Oct 2020 21:02:12

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:01:47', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '814d5c7b-3275-4f66-8efa-a0d5317f7a02'	System	23 Oct 2020 21:02:12
User entered 'No interference with activity (1)'	System	23 Oct 2020 21:02:12

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:01:50', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '814d5c7b-3275-4f66-8efa-a0d5317f7a02'	System	23 Oct 2020 21:02:12
User entered 'No interference with activity (1)'	System	23 Oct 2020 21:02:12

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:01:56', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '814d5c7b-3275-4f66-8efa-a0d5317f7a02'	System	23 Oct 2020 21:02:12
User entered 'Some interference with activity (2)'	System	23 Oct 2020 21:02:12

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:01:59', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '814d5c7b-3275-4f66-8efa-a0d5317f7a02' User entered 'None (0)'	System	23 Oct 2020 21:02:12
	System	23 Oct 2020 21:02:12

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:02:02', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '814d5c7b-3275-4f66-8efa-a0d5317f7a02' User entered 'None (0)'	System	23 Oct 2020 21:02:12
	System	23 Oct 2020 21:02:12

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:02:05', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '814d5c7b-3275-4f66-8efa-a0d5317f7a02'	System	23 Oct 2020 21:02:12
User entered 'No (N)'	System	23 Oct 2020 21:02:12

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-23T17:02:09', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '814d5c7b-3275-4f66-8efa-a0d5317f7a02' User entered '23 Oct 2020 17:02'	System	23 Oct 2020 21:02:12
	System	23 Oct 2020 21:02:12

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 6'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:31', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b5ee65f2-efaf-45da-8cf0-ad4ae345de84' User entered 'None (0)'	System	24 Oct 2020 23:43:57
	System	24 Oct 2020 23:43:57

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:37', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b5ee65f2-efaf-45da-8cf0-ad4ae345de84'	System	24 Oct 2020 23:43:57
User entered 'No interference with activity (1)'	System	24 Oct 2020 23:43:57

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:41', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b5ee65f2-efaf-45da-8cf0-ad4ae345de84'	System	24 Oct 2020 23:43:57
User entered 'No interference with activity (1)'	System	24 Oct 2020 23:43:57

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:44', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b5ee65f2-efaf-45da-8cf0-ad4ae345de84'	System	24 Oct 2020 23:43:57
User entered 'No interference with activity (1)'	System	24 Oct 2020 23:43:57

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:46', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b5ee65f2-efaf-45da-8cf0-ad4ae345de84' User entered 'None (0)'	System	24 Oct 2020 23:43:57
	System	24 Oct 2020 23:43:57

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:49', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b5ee65f2-efaf-45da-8cf0-ad4ae345de84' User entered 'None (0)'	System	24 Oct 2020 23:43:57
	System	24 Oct 2020 23:43:57

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:52', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b5ee65f2-efaf-45da-8cf0-ad4ae345de84' User entered 'No (N)'	System	24 Oct 2020 23:43:57
	System	24 Oct 2020 23:43:57

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-24T19:43:55', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b5ee65f2-efaf-45da-8cf0-ad4ae345de84' User entered '24 Oct 2020 19:43'	System	24 Oct 2020 23:43:57
	System	24 Oct 2020 23:43:57

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '25 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	19 Oct 2020 19:35:41
User entered 'Day 7'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:06:08', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '265979a4-22e5-42e6-9219-707b8c9d99a4' User entered 'None (0)'	System	25 Oct 2020 23:06:27
	System	25 Oct 2020 23:06:27

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:06:11', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '265979a4-22e5-42e6-9219-707b8c9d99a4' User entered 'None (0)'	System	25 Oct 2020 23:06:27
	System	25 Oct 2020 23:06:27

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:06:13', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '265979a4-22e5-42e6-9219-707b8c9d99a4' User entered 'None (0)'	System	25 Oct 2020 23:06:27
	System	25 Oct 2020 23:06:27

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:06:16', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '265979a4-22e5-42e6-9219-707b8c9d99a4' User entered 'None (0)'	System	25 Oct 2020 23:06:27
	System	25 Oct 2020 23:06:27

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:06:18', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '265979a4-22e5-42e6-9219-707b8c9d99a4' User entered 'None (0)'	System	25 Oct 2020 23:06:27
	System	25 Oct 2020 23:06:27

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:06:20', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '265979a4-22e5-42e6-9219-707b8c9d99a4' User entered 'None (0)'	System	25 Oct 2020 23:06:27
	System	25 Oct 2020 23:06:27

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:06:22', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '265979a4-22e5-42e6-9219-707b8c9d99a4' User entered 'No (N)'	System	25 Oct 2020 23:06:27
	System	25 Oct 2020 23:06:27

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-10-25T19:06:25', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '265979a4-22e5-42e6-9219-707b8c9d99a4' User entered '25 Oct 2020 19:06'	System	25 Oct 2020 23:06:27
	System	25 Oct 2020 23:06:27

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '25 Oct 2020 12:00'	System	19 Oct 2020 19:35:41

US3172406

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '26 Oct 2020 11:59'	System	19 Oct 2020 19:35:41

US3172406

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	29 Oct 2020 18:53:34

US3172406

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '27 Oct 2020'	Mariete Rendon (b) (4)	29 Oct 2020 18:53:34
	(b) (4)	

US3172406

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	29 Oct 2020 18:53:34

US3172406

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	29 Oct 2020 18:53:34

US3172406

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	03 Nov 2020 15:34:48
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	29 Oct 2020 18:53:37

US3172406

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '1'	System	03 Nov 2020 15:34:48
User entered empty.	System	29 Oct 2020 18:53:37

US3172406

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	03 Nov 2020 15:35:08

US3172406

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '2 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	03 Nov 2020 15:35:08

US3172406

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	03 Nov 2020 15:35:08

US3172406

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	03 Nov 2020 15:35:08

US3172406

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 21:24:55
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	03 Nov 2020 15:35:15

US3172406

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '1'	System	09 Nov 2020 21:24:55
User entered empty.	System	03 Nov 2020 15:35:15

US3172406

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 21:25:11

US3172406

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '09 Nov 2020'	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 21:25:11

US3172406

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 21:25:11

US3172406

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 21:25:11

US3172406

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Nov 2020 21:25:14

US3172406

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'I'	System	09 Nov 2020 21:25:14

US3172406

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:43:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '16 Nov 2020'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:43:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:43:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'VISIT2'	System	16 Nov 2020 21:43:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '16 Nov 2020'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '12:18'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '16 Nov 2020 12:18'	System	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '36.9' C	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '89'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'bpm'	System	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '16'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'breaths/min'	System	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '126'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'mmHg'	System	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '81'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'mmHg'	System	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 22:05:29
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '16 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 22:05:29
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '16:55' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 22:05:29
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '16 Nov 2020 16:55'	System	16 Nov 2020 22:05:29
User entered empty.	System	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 22:05:34
User entered '36.8' C reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 22:05:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Nov 2020 22:05:29
User entered '36.8' (non-conformant).	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 22:05:29
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Oral (Oral)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 22:05:29
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '82' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Nov 2020 22:05:29
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	16 Nov 2020 21:45:27
	(b) (4)	

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'bpm'	System	16 Nov 2020 22:05:29
User entered empty.	System	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '16' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 22:05:29
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'breaths/min'	System	16 Nov 2020 22:05:29
User entered empty.	System	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '137' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 22:05:29
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'mmHg'	System	16 Nov 2020 22:05:29
User entered empty.	System	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '78' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 22:05:29
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:26

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'mmHg'	System	16 Nov 2020 22:05:29
User entered empty.	System	16 Nov 2020 21:45:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:43:50

US3172406

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '16 Nov 2020'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:43:50

US3172406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:39:26

US3172406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:39:26

US3172406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	16 Nov 2020 21:39:26
	(b) (4)	

US3172406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'MRNA-1273 OR PLACEBO'	System	16 Nov 2020 21:39:26

US3172406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '16 Nov 2020'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:39:26

US3172406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '16:25'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:39:26

US3172406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '16 Nov 2020 16:25'	System	16 Nov 2020 21:39:26

US3172406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Left Arm (LEFT ARM)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:39:26

US3172406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'ONCE'	System	16 Nov 2020 21:39:26

US3172406

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:26

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'INTRAMUSCULAR'	System	16 Nov 2020 21:39:26

US3172406

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:44:08

US3172406

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '16 Nov 2020'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:44:08

US3172406

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '13:00'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:44:08

US3172406

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '16 Nov 2020 13:00'	System	16 Nov 2020 21:44:08

US3172406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:31:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '16 Nov 2020'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:44:23

US3172406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:44:23

US3172406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:44:23

US3172406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '13:03'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:44:23

US3172406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '16 Nov 2020 13:03'	System	16 Nov 2020 21:44:23

US3172406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:26

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:44:23

US3172406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:44:23

US3172406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:44:23

US3172406

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered empty.	System	16 Nov 2020 21:44:23

US3172406

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Nov 2020 21:44:27

US3172406

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'I'	System	16 Nov 2020 21:44:27

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:55:51', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2a3fed30-521f-4699-8564-788303cc9436' User entered 'Yes (Y)'	System	16 Nov 2020 21:56:13
	System	16 Nov 2020 21:56:13

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:55:58', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2a3fed30-521f-4699-8564-788303cc9436' User entered '98.3'	System	16 Nov 2020 21:56:13
	System	16 Nov 2020 21:56:13

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:56:03', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2a3fed30-521f-4699-8564-788303cc9436' User entered 'No (N)'	System	16 Nov 2020 21:56:13
	System	16 Nov 2020 21:56:13

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:56:09', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2a3fed30-521f-4699-8564-788303cc9436' User entered '16 Nov 2020 16:56'	System	16 Nov 2020 21:56:13
	System	16 Nov 2020 21:56:13

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '16 Nov 2020 16:45'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '16 Nov 2020 19:15'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:16:47', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b6076c21-58e9-4838-995b-8e6174a9d0a0' User entered 'Yes (Y)'	System	17 Nov 2020 05:17:27
	System	17 Nov 2020 05:17:27

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:16:56', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b6076c21-58e9-4838-995b-8e6174a9d0a0' User entered '98.6'	System	17 Nov 2020 05:17:27
	System	17 Nov 2020 05:17:27

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:17:01', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b6076c21-58e9-4838-995b-8e6174a9d0a0'	System	17 Nov 2020 05:17:27
User entered 'Yes (Y)'	System	17 Nov 2020 05:17:27

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'See conmed log.' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 02:24:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:17:12', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b6076c21-58e9-4838-995b-8e6174a9d0a0' User entered '1'	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:12:42
	System	17 Nov 2020 05:17:27
	System	17 Nov 2020 05:17:27
	System	17 Nov 2020 05:17:27

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:17:12', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b6076c21-58e9-4838-995b-8e6174a9d0a0' User entered '0'	System	17 Nov 2020 05:17:27
	System	17 Nov 2020 05:17:27

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:17:22', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b6076c21-58e9-4838-995b-8e6174a9d0a0' User entered '17 Nov 2020 00:17'	System	17 Nov 2020 05:17:27
	System	17 Nov 2020 05:17:27

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '16 Nov 2020 20:10'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 2'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T23:59:50', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'aed1618d-31fc-4225-92d8-ad32d67aa1db' User entered 'Yes (Y)'	System	18 Nov 2020 05:00:19
	System	18 Nov 2020 05:00:19

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:00:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'aed1618d-31fc-4225-92d8-ad32d67aa1db' User entered '99.6'	System	18 Nov 2020 05:00:19
	System	18 Nov 2020 05:00:19

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:00:04', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'aed1618d-31fc-4225-92d8-ad32d67aa1db' User entered 'Yes (Y)'	System	18 Nov 2020 05:00:19
	System	18 Nov 2020 05:00:19

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'see conmed log' (Site from System).	(b) (4), (b) (6)	24 Nov 2020 02:25:08
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:00:09', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'aed1618d-31fc-4225-92d8-ad32d67aa1db' User entered '1'	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:12:53
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	18 Nov 2020 05:00:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:00:09', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'aed1618d-31fc-4225-92d8-ad32d67aa1db' User entered '1'	System	18 Nov 2020 05:00:19
User entered '1'	System	18 Nov 2020 05:00:19

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:00:09', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'aed1618d-31fc-4225-92d8-ad32d67aa1db' User entered '0'	System	18 Nov 2020 05:00:19
	System	18 Nov 2020 05:00:19

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:00:15', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'aed1618d-31fc-4225-92d8-ad32d67aa1db' User entered '18 Nov 2020 00:00'	System	18 Nov 2020 05:00:19
	System	18 Nov 2020 05:00:19

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 3'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T23:59:25', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '1826f2cf-559a-4c7c-afb0-8eac41b0da9c' User entered 'Yes (Y)'	System	19 Nov 2020 05:00:45
	System	19 Nov 2020 05:00:45

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T23:59:38', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '1826f2cf-559a-4c7c-afb0-8eac41b0da9c' User entered '97.8'	System	19 Nov 2020 05:00:45
	System	19 Nov 2020 05:00:45

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:00:28', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '1826f2cf-559a-4c7c-afb0-8eac41b0da9c' User entered 'No (N)'	System	19 Nov 2020 05:00:45
	System	19 Nov 2020 05:00:45

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:00:42', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '1826f2cf-559a-4c7c-afb0-8eac41b0da9c' User entered '19 Nov 2020 00:00'	System	19 Nov 2020 05:00:45
	System	19 Nov 2020 05:00:45

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 4'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T23:59:27', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a73d0424-e158-40d1-8f25-b96461cd32da' User entered 'Yes (Y)'	System	20 Nov 2020 04:59:52
	System	20 Nov 2020 04:59:52

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T23:59:34', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a73d0424-e158-40d1-8f25-b96461cd32da' User entered '98.6'	System	20 Nov 2020 04:59:52
	System	20 Nov 2020 04:59:52

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T23:59:47', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a73d0424-e158-40d1-8f25-b96461cd32da' User entered 'No (N)'	System	20 Nov 2020 04:59:52
	System	20 Nov 2020 04:59:52

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T23:59:51', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a73d0424-e158-40d1-8f25-b96461cd32da' User entered '19 Nov 2020 23:59'	System	20 Nov 2020 04:59:52
	System	20 Nov 2020 04:59:52

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 5'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:16:53', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '63d0e4f0-7cd5-422c-b428-e6122193585b' User entered 'Yes (Y)'	System	21 Nov 2020 03:19:12
	System	21 Nov 2020 03:19:12

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:17:03', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '63d0e4f0-7cd5-422c-b428-e6122193585b' User entered '98.8'	System	21 Nov 2020 03:19:12
	System	21 Nov 2020 03:19:12

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:17:11', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '63d0e4f0-7cd5-422c-b428-e6122193585b' User entered 'Yes (Y)'	System	21 Nov 2020 03:19:12
	System	21 Nov 2020 03:19:12

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Reported in error subject asymptomatic' (Site from System).	(b) (4), (b) (6)	01 Dec 2020 03:05:49
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:17:28', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '63d0e4f0-7cd5-422c-b428-e6122193585b' User entered '1'	Mariete Rendon (b) (4) (b) (4)	24 Nov 2020 19:13:07
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	21 Nov 2020 03:19:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:17:28', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '63d0e4f0-7cd5-422c-b428-e6122193585b' User entered '1'	System	21 Nov 2020 03:19:12
User entered '1'	System	21 Nov 2020 03:19:12

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:17:28', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '63d0e4f0-7cd5-422c-b428-e6122193585b' User entered '0'	System	21 Nov 2020 03:19:12
	System	21 Nov 2020 03:19:12

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:17:43', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '63d0e4f0-7cd5-422c-b428-e6122193585b' User entered '20 Nov 2020 22:17'	System	21 Nov 2020 03:19:12
	System	21 Nov 2020 03:19:12

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 6'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-21T23:59:27', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '79e6d691-1061-43a7-bf15-a58bbb865aae'	System	22 Nov 2020 04:59:46
User entered 'Yes (Y)'	System	22 Nov 2020 04:59:46

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-21T23:59:33', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '79e6d691-1061-43a7-bf15-a58bbb865aae' User entered '98.6'	System	22 Nov 2020 04:59:46
	System	22 Nov 2020 04:59:46

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-21T23:59:37', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '79e6d691-1061-43a7-bf15-a58bbb865aae'	System	22 Nov 2020 04:59:46
User entered 'No (N)'	System	22 Nov 2020 04:59:46

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-21T23:59:42', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '79e6d691-1061-43a7-bf15-a58bbb865aae'	System	22 Nov 2020 04:59:46
User entered '21 Nov 2020 23:59'	System	22 Nov 2020 04:59:46

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 7'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:38:13', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5c7ec12a-b731-40ef-92d5-aecfd04204e9' User entered 'Yes (Y)'	System	23 Nov 2020 05:38:35
	System	23 Nov 2020 05:38:35

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:38:20', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5c7ec12a-b731-40ef-92d5-aecfd04204e9' User entered '98.0'	System	23 Nov 2020 05:38:35
	System	23 Nov 2020 05:38:35

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:38:23', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5c7ec12a-b731-40ef-92d5-aecfd04204e9' User entered 'No (N)'	System	23 Nov 2020 05:38:35
	System	23 Nov 2020 05:38:35

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:38:28', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5c7ec12a-b731-40ef-92d5-aecfd04204e9' User entered '23 Nov 2020 00:38'	System	23 Nov 2020 05:38:35
	System	23 Nov 2020 05:38:35

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:56:22', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'ed307235-60b9-40a7-9771-b7650aeb9c3f'	System	16 Nov 2020 21:56:42
User entered 'Does not interfere with activity (2)'	System	16 Nov 2020 21:56:42

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:56:25', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'ed307235-60b9-40a7-9771-b7650aeb9c3f' User entered 'No (N)'	System	16 Nov 2020 21:56:42
	System	16 Nov 2020 21:56:42

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:56:31', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'ed307235-60b9-40a7-9771-b7650aeb9c3f' User entered 'No (N)'	System	16 Nov 2020 21:56:42
	System	16 Nov 2020 21:56:42

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:56:35', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'ed307235-60b9-40a7-9771-b7650aeb9c3f'	System	16 Nov 2020 21:56:42
User entered 'None (1)'	System	16 Nov 2020 21:56:42

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:56:38', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'ed307235-60b9-40a7-9771-b7650aeb9c3f' User entered '16 Nov 2020 16:56'	System	16 Nov 2020 21:56:42
	System	16 Nov 2020 21:56:42

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '16 Nov 2020 16:45'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '16 Nov 2020 19:15'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:17:45', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '790552be-bb9c-4b84-a5e3-6d6692f1e629'	System	17 Nov 2020 05:18:22
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	17 Nov 2020 05:18:22

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:17:50', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '790552be-bb9c-4b84-a5e3-6d6692f1e629' User entered 'No (N)'	System	17 Nov 2020 05:18:22
	System	17 Nov 2020 05:18:22

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:17:59', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '790552be-bb9c-4b84-a5e3-6d6692f1e629' User entered 'No (N)'	System	17 Nov 2020 05:18:22
	System	17 Nov 2020 05:18:22

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:18:09', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '790552be-bb9c-4b84-a5e3-6d6692f1e629' User entered 'None (1)'	System	17 Nov 2020 05:18:22
	System	17 Nov 2020 05:18:22

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:18:19', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '790552be-bb9c-4b84-a5e3-6d6692f1e629' User entered '17 Nov 2020 00:18'	System	17 Nov 2020 05:18:22
	System	17 Nov 2020 05:18:22

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '16 Nov 2020 20:10'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 2'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:00:24', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '12efec7e-be77-43ec-b17d-0ae506ccc6a8'	System	18 Nov 2020 05:01:36
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	18 Nov 2020 05:01:36

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:00:28', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '12efec7e-be77-43ec-b17d-0ae506ccc6a8' User entered 'No (N)'	System	18 Nov 2020 05:01:36
	System	18 Nov 2020 05:01:36

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:00:34', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '12efec7e-be77-43ec-b17d-0ae506ccc6a8' User entered 'Yes (Y)'	System	18 Nov 2020 05:01:36
	System	18 Nov 2020 05:01:36

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:01:23', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '12efec7e-be77-43ec-b17d-0ae506ccc6a8' User entered '100'	System	18 Nov 2020 05:01:36
	System	18 Nov 2020 05:01:36

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:00:58', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '12efec7e-be77-43ec-b17d-0ae506ccc6a8' User entered 'None (1)'	System	18 Nov 2020 05:01:36
	System	18 Nov 2020 05:01:36

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:01:26', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '12efec7e-be77-43ec-b17d-0ae506ccc6a8' User entered '18 Nov 2020 00:01'	System	18 Nov 2020 05:01:36
	System	18 Nov 2020 05:01:36

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 3'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:00:57', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a516aa13-7863-4a51-9fa0-971c18e8b31a'	System	19 Nov 2020 05:01:52
User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 05:01:52

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:01:03', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a516aa13-7863-4a51-9fa0-971c18e8b31a' User entered 'No (N)'	System	19 Nov 2020 05:01:52
	System	19 Nov 2020 05:01:52

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:01:14', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a516aa13-7863-4a51-9fa0-971c18e8b31a' User entered 'No (N)'	System	19 Nov 2020 05:01:52
	System	19 Nov 2020 05:01:52

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:01:36', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a516aa13-7863-4a51-9fa0-971c18e8b31a' User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 05:01:52
	System	19 Nov 2020 05:01:52

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:01:47', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a516aa13-7863-4a51-9fa0-971c18e8b31a' User entered '19 Nov 2020 00:01'	System	19 Nov 2020 05:01:52
	System	19 Nov 2020 05:01:52

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 4'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T23:59:59', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bdaabc12-41fb-42a4-b0f7-c3119ba729eb'	System	20 Nov 2020 05:00:38
User entered 'Does not interfere with activity (2)'	System	20 Nov 2020 05:00:38

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T00:00:03', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bdaabc12-41fb-42a4-b0f7-c3119ba729eb' User entered 'No (N)'	System	20 Nov 2020 05:00:38
	System	20 Nov 2020 05:00:38

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T00:00:11', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bdaabc12-41fb-42a4-b0f7-c3119ba729eb' User entered 'No (N)'	System	20 Nov 2020 05:00:38
	System	20 Nov 2020 05:00:38

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T00:00:19', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bdaabc12-41fb-42a4-b0f7-c3119ba729eb'	System	20 Nov 2020 05:00:38
User entered 'Does not interfere with activity (2)'	System	20 Nov 2020 05:00:38

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T00:00:35', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bdaabc12-41fb-42a4-b0f7-c3119ba729eb' User entered '20 Nov 2020 00:00'	System	20 Nov 2020 05:00:38
	System	20 Nov 2020 05:00:38

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 5'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:16:15', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'de09c6aa-136b-44f4-9afc-a16d5b2fce15'	System	21 Nov 2020 03:19:09
User entered 'Does not interfere with activity (2)'	System	21 Nov 2020 03:19:09

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:16:21', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'de09c6aa-136b-44f4-9afc-a16d5b2fce15' User entered 'No (N)'	System	21 Nov 2020 03:19:09
	System	21 Nov 2020 03:19:09

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:16:25', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'de09c6aa-136b-44f4-9afc-a16d5b2fce15' User entered 'No (N)'	System	21 Nov 2020 03:19:09
	System	21 Nov 2020 03:19:09

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:16:31', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'de09c6aa-136b-44f4-9afc-a16d5b2fce15'	System	21 Nov 2020 03:19:09
User entered 'Does not interfere with activity (2)'	System	21 Nov 2020 03:19:09

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:16:44', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'de09c6aa-136b-44f4-9afc-a16d5b2fce15' User entered '20 Nov 2020 22:16'	System	21 Nov 2020 03:19:09
	System	21 Nov 2020 03:19:09

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 6'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-21T23:59:48', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '34a2238f-ecff-4ceb-a5bd-430c324ab169'	System	22 Nov 2020 05:00:17
User entered 'Does not interfere with activity (2)'	System	22 Nov 2020 05:00:17

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-21T23:59:57', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '34a2238f-ecff-4ceb-a5bd-430c324ab169'	System	22 Nov 2020 05:00:17
User entered 'No (N)'	System	22 Nov 2020 05:00:17

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-22T00:00:02', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '34a2238f-ecff-4ceb-a5bd-430c324ab169' User entered 'No (N)'	System	22 Nov 2020 05:00:17
	System	22 Nov 2020 05:00:17

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-22T00:00:07', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '34a2238f-ecff-4ceb-a5bd-430c324ab169'	System	22 Nov 2020 05:00:17
User entered 'None (1)'	System	22 Nov 2020 05:00:17

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-22T00:00:11', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '34a2238f-ecff-4ceb-a5bd-430c324ab169' User entered '22 Nov 2020 00:00'	System	22 Nov 2020 05:00:17
	System	22 Nov 2020 05:00:17

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 7'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:38:34', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '1bc07bd1-398a-484e-947c-c6a3265fed25'	System	23 Nov 2020 05:39:17
User entered 'Does not interfere with activity (2)'	System	23 Nov 2020 05:39:17

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:38:47', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '1bc07bd1-398a-484e-947c-c6a3265fed25' User entered 'No (N)'	System	23 Nov 2020 05:39:17
	System	23 Nov 2020 05:39:17

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:39:03', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '1bc07bd1-398a-484e-947c-c6a3265fed25' User entered 'No (N)'	System	23 Nov 2020 05:39:17
	System	23 Nov 2020 05:39:17

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:39:10', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '1bc07bd1-398a-484e-947c-c6a3265fed25'	System	23 Nov 2020 05:39:17
User entered 'Does not interfere with activity (2)'	System	23 Nov 2020 05:39:17

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:39:14', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '1bc07bd1-398a-484e-947c-c6a3265fed25' User entered '23 Nov 2020 00:39'	System	23 Nov 2020 05:39:17
	System	23 Nov 2020 05:39:17

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:56:46', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b2065ac2-8ab5-4e77-819f-a816481dc795' User entered 'None (0)'	System	16 Nov 2020 21:57:17
	System	16 Nov 2020 21:57:17

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:56:50', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b2065ac2-8ab5-4e77-819f-a816481dc795' User entered 'None (0)'	System	16 Nov 2020 21:57:17
	System	16 Nov 2020 21:57:17

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:56:53', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b2065ac2-8ab5-4e77-819f-a816481dc795' User entered 'None (0)'	System	16 Nov 2020 21:57:17
	System	16 Nov 2020 21:57:17

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:56:58', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b2065ac2-8ab5-4e77-819f-a816481dc795' User entered 'None (0)'	System	16 Nov 2020 21:57:17
	System	16 Nov 2020 21:57:17

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:57:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b2065ac2-8ab5-4e77-819f-a816481dc795' User entered 'None (0)'	System	16 Nov 2020 21:57:17
	System	16 Nov 2020 21:57:17

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:57:05', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b2065ac2-8ab5-4e77-819f-a816481dc795' User entered 'None (0)'	System	16 Nov 2020 21:57:17
	System	16 Nov 2020 21:57:17

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:57:08', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b2065ac2-8ab5-4e77-819f-a816481dc795' User entered 'No (N)'	System	16 Nov 2020 21:57:17
	System	16 Nov 2020 21:57:17

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-16T16:57:12', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b2065ac2-8ab5-4e77-819f-a816481dc795' User entered '16 Nov 2020 16:57'	System	16 Nov 2020 21:57:17
	System	16 Nov 2020 21:57:17

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '16 Nov 2020 16:45'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '16 Nov 2020 19:15'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 1, after vaccination (at home)'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:18:58', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '019cf27b-17a0-4023-9878-2a2c5ad91a8e'	System	17 Nov 2020 05:20:23
User entered 'No interference with activity (1)'	System	17 Nov 2020 05:20:23

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:19:06', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '019cf27b-17a0-4023-9878-2a2c5ad91a8e' User entered 'Some interference with activity (2)'	System	17 Nov 2020 05:20:23
	System	17 Nov 2020 05:20:23

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:19:10', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '019cf27b-17a0-4023-9878-2a2c5ad91a8e' User entered 'Some interference with activity (2)'	System	17 Nov 2020 05:20:23
	System	17 Nov 2020 05:20:23

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:19:18', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '019cf27b-17a0-4023-9878-2a2c5ad91a8e' User entered 'Some interference with activity (2)'	System	17 Nov 2020 05:20:23
	System	17 Nov 2020 05:20:23

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:19:21', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '019cf27b-17a0-4023-9878-2a2c5ad91a8e' User entered 'None (0)'	System	17 Nov 2020 05:20:23
	System	17 Nov 2020 05:20:23

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:19:28', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '019cf27b-17a0-4023-9878-2a2c5ad91a8e'	System	17 Nov 2020 05:20:23
User entered 'No interference with activity (1)'	System	17 Nov 2020 05:20:23

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:20:08', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '019cf27b-17a0-4023-9878-2a2c5ad91a8e' User entered 'No (N)'	System	17 Nov 2020 05:20:23
	System	17 Nov 2020 05:20:23

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-17T00:20:20', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '019cf27b-17a0-4023-9878-2a2c5ad91a8e' User entered '17 Nov 2020 00:20'	System	17 Nov 2020 05:20:23
	System	17 Nov 2020 05:20:23

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '16 Nov 2020 20:10'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '17 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 2'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:01:36', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5aa7ca85-4ec2-4b3f-bd9c-2a482c611003'	System	18 Nov 2020 05:02:25
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	18 Nov 2020 05:02:25

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:01:42', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5aa7ca85-4ec2-4b3f-bd9c-2a482c611003'	System	18 Nov 2020 05:02:25
User entered 'Some interference with activity (2)'	System	18 Nov 2020 05:02:25

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:01:47', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5aa7ca85-4ec2-4b3f-bd9c-2a482c611003'	System	18 Nov 2020 05:02:25
User entered 'Some interference with activity (2)'	System	18 Nov 2020 05:02:25

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:01:52', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5aa7ca85-4ec2-4b3f-bd9c-2a482c611003'	System	18 Nov 2020 05:02:25
User entered 'Some interference with activity (2)'	System	18 Nov 2020 05:02:25

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:02:08', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5aa7ca85-4ec2-4b3f-bd9c-2a482c611003'	System	18 Nov 2020 05:02:25
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	18 Nov 2020 05:02:25

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:02:13', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5aa7ca85-4ec2-4b3f-bd9c-2a482c611003'	System	18 Nov 2020 05:02:25
User entered 'Some interference with activity not requiring medical attention (2)'	System	18 Nov 2020 05:02:25

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:02:18', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5aa7ca85-4ec2-4b3f-bd9c-2a482c611003' User entered 'No (N)'	System	18 Nov 2020 05:02:25
	System	18 Nov 2020 05:02:25

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-18T00:02:22', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5aa7ca85-4ec2-4b3f-bd9c-2a482c611003' User entered '18 Nov 2020 00:02'	System	18 Nov 2020 05:02:25
	System	18 Nov 2020 05:02:25

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '17 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '18 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 3'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:02:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '896f99b7-de68-4bc0-a82b-1e3b0ea396a1'	System	19 Nov 2020 05:02:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Nov 2020 05:02:49

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:02:08', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '896f99b7-de68-4bc0-a82b-1e3b0ea396a1'	System	19 Nov 2020 05:02:49
User entered 'No interference with activity (1)'	System	19 Nov 2020 05:02:49

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:02:12', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '896f99b7-de68-4bc0-a82b-1e3b0ea396a1'	System	19 Nov 2020 05:02:49
User entered 'No interference with activity (1)'	System	19 Nov 2020 05:02:49

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:02:17', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '896f99b7-de68-4bc0-a82b-1e3b0ea396a1' User entered 'No interference with activity (1)'	System	19 Nov 2020 05:02:49
	System	19 Nov 2020 05:02:49

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:02:21', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '896f99b7-de68-4bc0-a82b-1e3b0ea396a1' User entered 'None (0)'	System	19 Nov 2020 05:02:49
	System	19 Nov 2020 05:02:49

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:02:25', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '896f99b7-de68-4bc0-a82b-1e3b0ea396a1' User entered 'None (0)'	System	19 Nov 2020 05:02:49
	System	19 Nov 2020 05:02:49

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:02:32', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '896f99b7-de68-4bc0-a82b-1e3b0ea396a1' User entered 'No (N)'	System	19 Nov 2020 05:02:49
	System	19 Nov 2020 05:02:49

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-19T00:02:45', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '896f99b7-de68-4bc0-a82b-1e3b0ea396a1' User entered '19 Nov 2020 00:02'	System	19 Nov 2020 05:02:49
	System	19 Nov 2020 05:02:49

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '18 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 4'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T00:00:46', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '24157ca1-e38c-4314-bf44-c59a0972379a' User entered 'No interference with activity (1)'	System	20 Nov 2020 05:01:37
	System	20 Nov 2020 05:01:37

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T00:00:51', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '24157ca1-e38c-4314-bf44-c59a0972379a' User entered 'No interference with activity (1)'	System	20 Nov 2020 05:01:37
	System	20 Nov 2020 05:01:37

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T00:00:54', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '24157ca1-e38c-4314-bf44-c59a0972379a' User entered 'No interference with activity (1)'	System	20 Nov 2020 05:01:37
	System	20 Nov 2020 05:01:37

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T00:00:58', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '24157ca1-e38c-4314-bf44-c59a0972379a' User entered 'No interference with activity (1)'	System	20 Nov 2020 05:01:37
	System	20 Nov 2020 05:01:37

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T00:01:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '24157ca1-e38c-4314-bf44-c59a0972379a'	System	20 Nov 2020 05:01:37
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Nov 2020 05:01:37

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T00:01:25', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '24157ca1-e38c-4314-bf44-c59a0972379a' User entered 'No interference with activity (1)'	System	20 Nov 2020 05:01:37
	System	20 Nov 2020 05:01:37

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T00:01:30', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '24157ca1-e38c-4314-bf44-c59a0972379a' User entered 'No (N)'	System	20 Nov 2020 05:01:37
	System	20 Nov 2020 05:01:37

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T00:01:33', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '24157ca1-e38c-4314-bf44-c59a0972379a' User entered '20 Nov 2020 00:01'	System	20 Nov 2020 05:01:37
	System	20 Nov 2020 05:01:37

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '19 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '20 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 5'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:17:55', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'dcf6d8a0-b20c-4f02-81dd-db651b54cc0b'	System	21 Nov 2020 03:24:27
User entered 'No interference with activity (1)'	System	21 Nov 2020 03:24:27

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:18:02', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'dcf6d8a0-b20c-4f02-81dd-db651b54cc0b'	System	21 Nov 2020 03:24:27
User entered 'No interference with activity (1)'	System	21 Nov 2020 03:24:27

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:18:07', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'dcf6d8a0-b20c-4f02-81dd-db651b54cc0b'	System	21 Nov 2020 03:24:27
User entered 'No interference with activity (1)'	System	21 Nov 2020 03:24:27

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:18:12', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'dcf6d8a0-b20c-4f02-81dd-db651b54cc0b' User entered 'No interference with activity (1)'	System	21 Nov 2020 03:24:27
	System	21 Nov 2020 03:24:27

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:24:01', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'dcf6d8a0-b20c-4f02-81dd-db651b54cc0b'	System	21 Nov 2020 03:24:27
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	21 Nov 2020 03:24:27

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:24:06', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'dcf6d8a0-b20c-4f02-81dd-db651b54cc0b' User entered 'No interference with activity (1)'	System	21 Nov 2020 03:24:27
	System	21 Nov 2020 03:24:27

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:24:14', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'dcf6d8a0-b20c-4f02-81dd-db651b54cc0b' User entered 'No (N)'	System	21 Nov 2020 03:24:27
	System	21 Nov 2020 03:24:27

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-20T22:24:24', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'dcf6d8a0-b20c-4f02-81dd-db651b54cc0b' User entered '20 Nov 2020 22:24'	System	21 Nov 2020 03:24:27
	System	21 Nov 2020 03:24:27

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '20 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '21 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 6'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-22T00:00:24', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '04d7a2f2-1800-4780-b7eb-7eabd3e07b5d' User entered 'No interference with activity (1)'	System	22 Nov 2020 05:03:08
	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-22T00:00:29', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '04d7a2f2-1800-4780-b7eb-7eabd3e07b5d'	System	22 Nov 2020 05:03:08
User entered 'No interference with activity (1)'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-22T00:01:53', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '04d7a2f2-1800-4780-b7eb-7eabd3e07b5d' User entered 'No interference with activity (1)'	System	22 Nov 2020 05:03:08
	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-22T00:01:42', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '04d7a2f2-1800-4780-b7eb-7eabd3e07b5d' User entered 'No interference with activity (1)'	System	22 Nov 2020 05:03:08
	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-22T00:01:17', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '04d7a2f2-1800-4780-b7eb-7eabd3e07b5d'	System	22 Nov 2020 05:03:08
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-22T00:01:23', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '04d7a2f2-1800-4780-b7eb-7eabd3e07b5d' User entered 'No interference with activity (1)'	System	22 Nov 2020 05:03:08
	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-22T00:01:28', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '04d7a2f2-1800-4780-b7eb-7eabd3e07b5d' User entered 'No (N)'	System	22 Nov 2020 05:03:08
	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-22T00:02:02', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '04d7a2f2-1800-4780-b7eb-7eabd3e07b5d' User entered '22 Nov 2020 00:02'	System	22 Nov 2020 05:03:08
	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '21 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '22 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	16 Nov 2020 21:39:26
User entered 'Day 7'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:39:20', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bc281477-d758-429e-a9c9-70d2e685b9ed' User entered 'None (0)'	System	23 Nov 2020 05:40:04
	System	23 Nov 2020 05:40:04

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:39:23', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bc281477-d758-429e-a9c9-70d2e685b9ed'	System	23 Nov 2020 05:40:04
User entered 'No interference with activity (1)'	System	23 Nov 2020 05:40:04

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:39:27', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bc281477-d758-429e-a9c9-70d2e685b9ed'	System	23 Nov 2020 05:40:04
User entered 'No interference with activity (1)'	System	23 Nov 2020 05:40:04

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:39:30', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bc281477-d758-429e-a9c9-70d2e685b9ed'	System	23 Nov 2020 05:40:04
User entered 'No interference with activity (1)'	System	23 Nov 2020 05:40:04

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:39:41', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bc281477-d758-429e-a9c9-70d2e685b9ed' User entered 'None (0)'	System	23 Nov 2020 05:40:04
	System	23 Nov 2020 05:40:04

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:39:53', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bc281477-d758-429e-a9c9-70d2e685b9ed'	System	23 Nov 2020 05:40:04
User entered 'No interference with activity (1)'	System	23 Nov 2020 05:40:04

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:39:58', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bc281477-d758-429e-a9c9-70d2e685b9ed' User entered 'No (N)'	System	23 Nov 2020 05:40:04
	System	23 Nov 2020 05:40:04

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T00:40:02', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'bc281477-d758-429e-a9c9-70d2e685b9ed' User entered '23 Nov 2020 00:40'	System	23 Nov 2020 05:40:04
	System	23 Nov 2020 05:40:04

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '22 Nov 2020 12:00'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Nov 2020 11:59'	System	16 Nov 2020 21:39:26

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	22 Nov 2020 05:00:17
User entered 'Day 8'	System	22 Nov 2020 05:00:17

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:31:26

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T23:59:20', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '80bfc0b6-8d76-4cfb-954e-845750271493' User entered 'None (1)'	System	24 Nov 2020 04:59:32
	System	24 Nov 2020 04:59:32

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T23:59:27', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '80bfc0b6-8d76-4cfb-954e-845750271493' User entered '23 Nov 2020 23:59'	System	24 Nov 2020 04:59:32
	System	24 Nov 2020 04:59:32

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 05:00:17

US3172406

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 05:00:17

US3172406

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	22 Nov 2020 05:03:08
User entered 'Day 8'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:31:26

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T23:59:55', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'cebca262-07e9-4a67-bb1d-4f0d347923e3' User entered 'None (0)'	System	24 Nov 2020 05:00:04
	System	24 Nov 2020 05:00:04

US3172406

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-23T23:59:59', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'cebca262-07e9-4a67-bb1d-4f0d347923e3'	System	24 Nov 2020 05:00:04
User entered '23 Nov 2020 23:59'	System	24 Nov 2020 05:00:04

US3172406

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	22 Nov 2020 05:03:08
User entered 'Day 8'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:31:26

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-24T00:00:07', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'ac7576df-8c53-4391-9271-bcd40b067938' User entered 'None (0)'	System	24 Nov 2020 05:00:14
	System	24 Nov 2020 05:00:14

US3172406

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-24T00:00:11', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'ac7576df-8c53-4391-9271-bcd40b067938' User entered '24 Nov 2020 00:00'	System	24 Nov 2020 05:00:14
	System	24 Nov 2020 05:00:14

US3172406

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	22 Nov 2020 05:03:08
User entered 'Day 8'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:31:26

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-24T00:00:27', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'cc195c0f-fe36-4e45-abac-733e35f5173a' User entered 'None (0)'	System	24 Nov 2020 05:00:33
	System	24 Nov 2020 05:00:33

US3172406

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-24T00:00:31', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'cc195c0f-fe36-4e45-abac-733e35f5173a' User entered '24 Nov 2020 00:00'	System	24 Nov 2020 05:00:33
	System	24 Nov 2020 05:00:33

US3172406

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	22 Nov 2020 05:03:08
User entered 'Day 8'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 15:31:26

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-24T00:00:46', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '585dcef8-e4fa-4bdb-b599-8ab6b1d447ee' User entered 'None (0)'	System	24 Nov 2020 05:00:52
	System	24 Nov 2020 05:00:52

US3172406

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 05:03:08

US3172406

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-24T00:00:49', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '585dcef8-e4fa-4bdb-b599-8ab6b1d447ee' User entered '24 Nov 2020 00:00'	System	24 Nov 2020 05:00:52
	System	24 Nov 2020 05:00:52

US3172406

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	22 Nov 2020 05:00:17
User entered 'Day 8'	System	22 Nov 2020 05:00:17

US3172406

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:31:26

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-24T00:00:55', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '453105cb-a120-4455-ab9c-af34a9446ef6' User entered 'No (N)'	System	24 Nov 2020 05:01:01
	System	24 Nov 2020 05:01:01

US3172406

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-24T00:00:59', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '453105cb-a120-4455-ab9c-af34a9446ef6' User entered '24 Nov 2020 00:00'	System	24 Nov 2020 05:01:01
	System	24 Nov 2020 05:01:01

US3172406

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Nov 2020 12:00'	System	22 Nov 2020 05:00:17

US3172406

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Nov 2020 11:59'	System	22 Nov 2020 05:00:17

US3172406

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
Data entry locked.	System	23 Nov 2020 05:39:17
User entered 'Day 8'	System	23 Nov 2020 05:39:17

US3172406

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 15:31:26

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-24T00:01:04', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'e566a325-e388-4ee2-95aa-e84e51ca771e' User entered 'None (1)'	System	24 Nov 2020 05:01:20
	System	24 Nov 2020 05:01:20

US3172406

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-11-24T00:01:16', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'e566a325-e388-4ee2-95aa-e84e51ca771e' User entered '24 Nov 2020 00:01'	System	24 Nov 2020 05:01:20
	System	24 Nov 2020 05:01:20

US3172406

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Open Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '23 Nov 2020 12:00'	System	23 Nov 2020 05:39:17

US3172406

Folder: Diary Dose 2 (1)

Form: Underarm Gland_Day(8)

Generated On: 09 Jun 2021 15:31:26

[PC Close Date and Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:13:22
User entered '24 Nov 2020 11:59'	System	23 Nov 2020 05:39:17

US3172406

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 17:30:14

US3172406

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '23 Nov 2020'	Mariete Rendon (b) (4)	25 Nov 2020 17:30:14
	(b) (4)	

US3172406

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4)	25 Nov 2020 17:30:14
	(b) (4)	

US3172406

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 17:30:14

US3172406

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	25 Nov 2020 17:31:15

US3172406

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'I'	System	25 Nov 2020 17:31:15

US3172406

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	01 Dec 2020 15:30:54

US3172406

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '30 Nov 2020'	Mariete Rendon (b) (4)	01 Dec 2020 15:30:54
	(b) (4)	

US3172406

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	01 Dec 2020 15:30:54

US3172406

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	01 Dec 2020 15:30:54

US3172406

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	01 Dec 2020 15:30:57

US3172406

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'I'	System	01 Dec 2020 15:30:57

US3172406

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Dec 2020 16:40:45

US3172406

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '08 Dec 2020'	Jessie Downs (b) (4) (b) (4)	09 Dec 2020 16:40:45

US3172406

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	09 Dec 2020 16:40:45

US3172406

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	09 Dec 2020 16:40:45

US3172406

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	09 Dec 2020 16:41:12

US3172406

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'I'	System	09 Dec 2020 16:41:12

US3172406

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:27

US3172406

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '14 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:27

US3172406

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:27

US3172406

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'VISIT3'	System	14 Dec 2020 22:39:27

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '14 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '11:48'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '14 Dec 2020 11:48'	System	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '36.9' C	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '96'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'bpm'	System	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '14'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'breaths/min'	System	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '130'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'mmHg'	System	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '78'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'mmHg'	System	14 Dec 2020 22:39:56

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13

US3172406

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:26

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13

US3172406

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:26

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:40:03

US3172406

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:26

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:40:03

US3172406

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:40:15

US3172406

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '14 Dec 2020'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:40:15

US3172406

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '12:27'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:40:15

US3172406

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered '14 Dec 2020 12:27'	System	14 Dec 2020 22:40:15

US3172406

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Dec 2020 22:40:19

US3172406

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'I'	System	14 Dec 2020 22:40:19

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-12-16T00:23:27', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5b0af1b4-1349-42d9-8212-c21a8f53370c' User entered 'No (N)'	System	16 Dec 2020 05:23:48
	System	16 Dec 2020 05:23:48

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-12-16T00:23:35', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5b0af1b4-1349-42d9-8212-c21a8f53370c' User entered 'No (N)'	System	16 Dec 2020 05:23:48
	System	16 Dec 2020 05:23:48

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-12-16T00:23:45', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5b0af1b4-1349-42d9-8212-c21a8f53370c' User entered '16 Dec 2020 00:23:45'	System	16 Dec 2020 05:23:48
	System	16 Dec 2020 05:23:48

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-12-23T01:36:24', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '80a0017b-e376-4c15-872a-7c562250334e' User entered 'No (N)'	System	23 Dec 2020 06:36:47
	System	23 Dec 2020 06:36:47

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-12-23T01:36:35', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '80a0017b-e376-4c15-872a-7c562250334e' User entered 'No (N)'	System	23 Dec 2020 06:36:47
	System	23 Dec 2020 06:36:47

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-12-23T01:36:44', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '80a0017b-e376-4c15-872a-7c562250334e' User entered '23 Dec 2020 01:36:44'	System	23 Dec 2020 06:36:47
	System	23 Dec 2020 06:36:47

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-12-30T09:23:21', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7ef9e769-419c-45a7-88ec-7520638f2525'	System	30 Dec 2020 14:23:43
User entered 'No (N)'	System	30 Dec 2020 14:23:43

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-12-30T09:23:29', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7ef9e769-419c-45a7-88ec-7520638f2525' User entered 'No (N)'	System	30 Dec 2020 14:23:43
	System	30 Dec 2020 14:23:43

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2020-12-30T09:23:37', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7ef9e769-419c-45a7-88ec-7520638f2525' User entered '30 Dec 2020 09:23:37'	System	30 Dec 2020 14:23:43
	System	30 Dec 2020 14:23:43

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-01-06T02:07:46', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '143c965d-078c-423b-abb0-c637aa4262a2' User entered 'No (N)'	System	06 Jan 2021 07:08:28
	System	06 Jan 2021 07:08:28

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-01-06T02:08:19', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '143c965d-078c-423b-abb0-c637aa4262a2'	System	06 Jan 2021 07:08:28
User entered 'No (N)'	System	06 Jan 2021 07:08:28

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-01-06T02:08:27', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '143c965d-078c-423b-abb0-c637aa4262a2' User entered '06 Jan 2021 02:08:27'	System	06 Jan 2021 07:08:28
	System	06 Jan 2021 07:08:28

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-01-13T20:15:08', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7d962457-ad3a-41fa-af5e-99a96a0b0ded' User entered 'No (N)'	System	14 Jan 2021 01:15:18
	System	14 Jan 2021 01:15:18

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-01-13T20:15:11', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7d962457-ad3a-41fa-af5e-99a96a0b0ded' User entered 'No (N)'	System	14 Jan 2021 01:15:18
	System	14 Jan 2021 01:15:18

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-01-13T20:15:16', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '7d962457-ad3a-41fa-af5e-99a96a0b0ded' User entered '13 Jan 2021 20:15:16'	System	14 Jan 2021 01:15:18
	System	14 Jan 2021 01:15:18

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-01-20T00:01:47', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '73f8546f-9428-4ba4-b309-f500dc680ea3'	System	20 Jan 2021 05:02:15
User entered 'No (N)'	System	20 Jan 2021 05:02:15

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-01-20T00:01:53', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '73f8546f-9428-4ba4-b309-f500dc680ea3' User entered 'No (N)'	System	20 Jan 2021 05:02:15

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-01-20T00:01:57', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '73f8546f-9428-4ba4-b309-f500dc680ea3' User entered '20 Jan 2021 00:01:57'	System	20 Jan 2021 05:02:15
	System	20 Jan 2021 05:02:15

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-01-27T00:01:22', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a4afafda-c533-405c-94c3-9399acf270ac' User entered 'No (N)'	System	27 Jan 2021 05:01:59
	System	27 Jan 2021 05:01:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-01-27T00:01:26', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a4afafda-c533-405c-94c3-9399acf270ac'	System	27 Jan 2021 05:01:59
User entered 'No (N)'	System	27 Jan 2021 05:01:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-01-27T00:01:33', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'a4afafda-c533-405c-94c3-9399acf270ac' User entered '27 Jan 2021 00:01:33'	System	27 Jan 2021 05:01:59

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-02-03T00:01:16', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '84a557a4-a2a4-4e59-a092-6fd4f5884537'	System	03 Feb 2021 05:02:01
User entered 'No (N)'	System	03 Feb 2021 05:02:01

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-02-03T00:01:21', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '84a557a4-a2a4-4e59-a092-6fd4f5884537' User entered 'No (N)'	System	03 Feb 2021 05:02:01
	System	03 Feb 2021 05:02:01

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-02-03T00:01:31', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '84a557a4-a2a4-4e59-a092-6fd4f5884537' User entered '03 Feb 2021 00:01:31'	System	03 Feb 2021 05:02:01
	System	03 Feb 2021 05:02:01

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-02-10T01:11:28', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5dcb61b2-4794-4578-bc80-6244ac48d065'	System	10 Feb 2021 06:11:39
User entered 'No (N)'	System	10 Feb 2021 06:11:39

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-02-10T01:11:32', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5dcb61b2-4794-4578-bc80-6244ac48d065'	System	10 Feb 2021 06:11:39
User entered 'No (N)'	System	10 Feb 2021 06:11:39

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-02-10T01:11:36', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '5dcb61b2-4794-4578-bc80-6244ac48d065'	System	10 Feb 2021 06:11:39
User entered '10 Feb 2021 01:11:36'	System	10 Feb 2021 06:11:39

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-02-17T17:23:50', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2664f392-a1bb-45f9-b1e4-69a23285a1ed' User entered 'No (N)'	System	17 Feb 2021 22:24:01
	System	17 Feb 2021 22:24:01

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-02-17T17:23:55', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2664f392-a1bb-45f9-b1e4-69a23285a1ed' User entered 'No (N)'	System	17 Feb 2021 22:24:01
	System	17 Feb 2021 22:24:01

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-02-17T17:23:59', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '2664f392-a1bb-45f9-b1e4-69a23285a1ed' User entered '17 Feb 2021 17:23:59'	System	17 Feb 2021 22:24:01
	System	17 Feb 2021 22:24:01

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-02-24T00:04:10-05:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '400d53c6-2fc7-425a-a556-d201f36c2f50'	System	24 Feb 2021 05:05:28
User entered 'No (N)'	System	24 Feb 2021 05:05:28

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-02-24T00:04:14-05:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '400d53c6-2fc7-425a-a556-d201f36c2f50'	System	24 Feb 2021 05:05:28
User entered 'No (N)'	System	24 Feb 2021 05:05:28

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-02-24T00:04:20-05:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '400d53c6-2fc7-425a-a556-d201f36c2f50'	System	24 Feb 2021 05:05:28
User entered '24 Feb 2021 05:04:20'	System	24 Feb 2021 05:05:28

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-03T00:31:34-05:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'e1300ae2-13d5-4712-9df9-ed120b08dbdd'	System	03 Mar 2021 05:31:49
User entered 'No (N)'	System	03 Mar 2021 05:31:49

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-03T00:31:40-05:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'e1300ae2-13d5-4712-9df9-ed120b08dbdd'	System	03 Mar 2021 05:31:49
User entered 'No (N)'	System	03 Mar 2021 05:31:49

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-03T00:31:47-05:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'e1300ae2-13d5-4712-9df9-ed120b08dbdd' User entered '03 Mar 2021 00:31:47'	System	03 Mar 2021 05:31:49
	System	03 Mar 2021 05:31:49

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-10T01:11:30-05:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '8d7f9adf-9169-4eb6-b679-6de23c6df10d'	System	10 Mar 2021 06:11:43
User entered 'No (N)'	System	10 Mar 2021 06:11:43

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-10T01:11:34-05:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '8d7f9adf-9169-4eb6-b679-6de23c6df10d'	System	10 Mar 2021 06:11:43
User entered 'No (N)'	System	10 Mar 2021 06:11:43

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-10T01:11:39-05:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '8d7f9adf-9169-4eb6-b679-6de23c6df10d' User entered '10 Mar 2021 01:11:39'	System	10 Mar 2021 06:11:43
	System	10 Mar 2021 06:11:43

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-17T00:22:15-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '07405df7-b1c7-4c40-996e-ec6548f4c754'	System	17 Mar 2021 04:44:37
User entered 'No (N)'	System	17 Mar 2021 04:44:37

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-17T00:22:18-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '07405df7-b1c7-4c40-996e-ec6548f4c754'	System	17 Mar 2021 04:44:37
User entered 'No (N)'	System	17 Mar 2021 04:44:37

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-17T00:22:22-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '07405df7-b1c7-4c40-996e-ec6548f4c754'	System	17 Mar 2021 04:44:37
User entered '17 Mar 2021 00:22:22'	System	17 Mar 2021 04:44:37

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-24T00:02:21-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b77bff77-d34b-4b30-9810-fdaf923e5f05'	System	24 Mar 2021 04:03:26
User entered 'No (N)'	System	24 Mar 2021 04:03:26

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-24T00:02:26-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b77bff77-d34b-4b30-9810-fdaf923e5f05'	System	24 Mar 2021 04:03:26
User entered 'No (N)'	System	24 Mar 2021 04:03:26

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-24T00:02:33-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b77bff77-d34b-4b30-9810-fdaf923e5f05'	System	24 Mar 2021 04:03:26
User entered '24 Mar 2021 00:02:33'	System	24 Mar 2021 04:03:26

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-04-03T18:35:06-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'e496f6dd-3e4e-43e3-b8e2-7eeb5b9751c9'	System	03 Apr 2021 22:35:19
User entered 'No (N)'	System	03 Apr 2021 22:35:19

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-04-03T18:35:11-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'e496f6dd-3e4e-43e3-b8e2-7eeb5b9751c9' User entered 'No (N)'	System	03 Apr 2021 22:35:19
	System	03 Apr 2021 22:35:19

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-04-03T18:35:16-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'e496f6dd-3e4e-43e3-b8e2-7eeb5b9751c9'	System	03 Apr 2021 22:35:19
User entered '03 Apr 2021 18:35:16'	System	03 Apr 2021 22:35:19

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-04-07T17:17:18-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '50ce9149-c580-4268-bd92-4c976903c3cc' User entered 'No (N)'	System	07 Apr 2021 21:17:28
	System	07 Apr 2021 21:17:28

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-04-07T17:17:22-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '50ce9149-c580-4268-bd92-4c976903c3cc'	System	07 Apr 2021 21:17:28
User entered 'No (N)'	System	07 Apr 2021 21:17:28

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-04-07T17:17:26-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '50ce9149-c580-4268-bd92-4c976903c3cc' User entered '07 Apr 2021 17:17:26'	System	07 Apr 2021 21:17:28
	System	07 Apr 2021 21:17:28

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-04-14T00:04:45-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b4cec1b4-e05d-4cab-8f2f-728a29555fdc'	System	14 Apr 2021 04:06:27
User entered 'No (N)'	System	14 Apr 2021 04:06:27

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-04-14T00:04:49-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b4cec1b4-e05d-4cab-8f2f-728a29555fdc'	System	14 Apr 2021 04:06:27
User entered 'No (N)'	System	14 Apr 2021 04:06:27

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-04-14T00:04:53-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'b4cec1b4-e05d-4cab-8f2f-728a29555fdc'	System	14 Apr 2021 04:06:27
User entered '14 Apr 2021 00:04:53'	System	14 Apr 2021 04:06:27

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-04-21T01:59:06-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'c8e69ab1-7606-47cf-a3b4-914a29061111' User entered 'No (N)'	System	21 Apr 2021 05:59:15
	System	21 Apr 2021 05:59:15

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-04-21T01:59:09-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'c8e69ab1-7606-47cf-a3b4-914a29061111' User entered 'No (N)'	System	21 Apr 2021 05:59:15
	System	21 Apr 2021 05:59:15

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-04-21T01:59:13-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'c8e69ab1-7606-47cf-a3b4-914a29061111'	System	21 Apr 2021 05:59:15
User entered '21 Apr 2021 01:59:13'	System	21 Apr 2021 05:59:15

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-05-01T17:59:32-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '0aa6ab4e-aa54-4bc5-8d17-cdc3baa6978d'	System	01 May 2021 21:59:47
User entered 'No (N)'	System	01 May 2021 21:59:47

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-05-01T17:59:36-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '0aa6ab4e-aa54-4bc5-8d17-cdc3baa6978d' User entered 'No (N)'	System	01 May 2021 21:59:47

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-05-01T17:59:45-04:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: '0aa6ab4e-aa54-4bc5-8d17-cdc3baa6978d' User entered '01 May 2021 17:59:45'	System	01 May 2021 21:59:47
	System	01 May 2021 21:59:47

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '30 Nov 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '04 Dec 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '07 Dec 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '11 Dec 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '14 Dec 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '18 Dec 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '21 Dec 2022 00:01'	System	20 Nov 2020 13:06:57

US3172406

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:26

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:06:57
Amendment Manager: User entered '25 Dec 2022 23:59'	System	20 Nov 2020 13:06:57

US3172406

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:31:26

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:05:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-02T01:27:14-05:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'e8c523ce-32ee-4599-a4f7-ed7b422217f5'	System	02 Mar 2021 06:27:23
User entered 'No (N)'	System	02 Mar 2021 06:27:23

US3172406

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:31:26

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:05:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD301AEF-A622-4554-84C5-90BD3353D2B0)', Time: '2021-03-02T01:27:21-05:00', User OID: 'PatientReportedOutcome (US3172406)', ODM File OID: 'e8c523ce-32ee-4599-a4f7-ed7b422217f5'	System	02 Mar 2021 06:27:23
User entered '02 Mar 2021 01:27:21'	System	02 Mar 2021 06:27:23

US3172406

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	19 Jan 2021 20:14:01

US3172406

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 05:24:49
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Date confirmed as entered. ' (Site from System).	Jessie Downs (b) (4) (b) (4)	19 Jan 2021 20:15:26
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Jan 2021 20:14:01
User entered '19 Jan 2021'	Jessie Downs (b) (4) (b) (4)	19 Jan 2021 20:14:01

US3172406

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	19 Jan 2021 20:14:01

US3172406

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	19 Jan 2021 20:14:01

US3172406

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	19 Jan 2021 20:15:30

US3172406

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:32:13
User entered 'I'	System	19 Jan 2021 20:15:30

US3172406

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:14:22
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	03 Mar 2021 15:56:28
	(b) (4)	

US3172406

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:14:22
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered '16 Feb 2021'	Jessie Downs (b) (4)	03 Mar 2021 15:56:28
	(b) (4)	

US3172406

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:14:22
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	03 Mar 2021 15:56:28
	(b) (4)	

US3172406

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:14:22
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	03 Mar 2021 15:56:28
	(b) (4)	

US3172406

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:14:22
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	03 Mar 2021 15:56:33
	(b) (4)	

US3172406

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:14:22
User entered 'I'	System	03 Mar 2021 15:56:33

US3172406

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:06
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:41:41
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	16 Mar 2021 18:49:57
	(b) (4)	

US3172406

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:06
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:41:41
	(b) (4)	
User entered '16 Mar 2021'	Jessie Downs (b) (4)	16 Mar 2021 18:49:57
	(b) (4)	

US3172406

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:06
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:41:41
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	16 Mar 2021 18:49:57
	(b) (4)	

US3172406

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:26

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:41:41
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Mar 2021 18:49:57

US3172406

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:06
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:41:41
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	16 Mar 2021 18:50:56
	(b) (4)	

US3172406

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:26

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:11:06
User entered 'I'	System	16 Mar 2021 18:50:56

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	04 Mar 2021 22:16:06
	(b) (4)	

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	04 Mar 2021 22:16:06
	(b) (4)	

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 22:16:06

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:26

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered 'UNBLND_DECIDE'	System	04 Mar 2021 22:16:06

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:26

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:41:41
User closed query 'Per CDM RQ: Response noted. However, it appears the field has not been updated. Please confirm date of updated informed consent as Amendment 6 was not available until 29Dec2020. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 18:54:08
Query 'Per CDM RQ: Response noted. However, it appears the field has not been updated. Please confirm date of updated informed consent as Amendment 6 was not available until 29Dec2020. Thank you' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 14:47:05
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 14:46:51
User entered '06 Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 14:46:51
User opened query 'Per CDM RQ: Response noted. However, it appears the field has not been updated. Please confirm date of updated informed consent as Amendment 6 was not available until 29Dec2020. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 14:06:46
User closed query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 14:06:46

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:26

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	07 Apr 2021 21:18:13
User opened query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:28:42
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered '22 Dec 2020'	Jessie Downs (b) (4)	04 Mar 2021 22:16:30
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:26

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:41:41
User entered '0'	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 21:17:49
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:35:21

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:26

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	04 Mar 2021 22:16:30
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:26

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:41:41
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.	(b) (4), (b) (6)	16 Apr 2021 14:02:03
' (Site from DM). Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.	Jessie Downs (b) (4) (b) (4)	12 Apr 2021 16:54:19
' answered with 'Data was updated.' (Site from DM). User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.	Jessie Downs (b) (4) (b) (4) (b) (4), (b) (6)	12 Apr 2021 16:54:01 09 Apr 2021 22:15:18
' (Site from DM). User entered 'Amendment 5 (Amendment 5)' Amendment Manager inserted this DataPoint.	Jessie Downs (b) (4) (b) (4) System	07 Apr 2021 21:17:49 06 Mar 2021 20:35:21

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:26

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered '04 Mar 2021'	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 22:16:30

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:26

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'mRNA-1273 (mRNA-1273)'	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 22:16:30

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:26

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'mRNA-1273 (mRNA-1273)'	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 22:16:30

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:26

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'mRNA-1273 (mRNA-1273)'	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 22:16:30

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:26

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	04 Mar 2021 22:16:30
	(b) (4)	

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:26

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	04 Mar 2021 22:16:30

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:31:26

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered empty.	System	04 Mar 2021 22:16:30

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 22:15:55

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered '04 Mar 2021'	Jessie Downs (b) (4)	04 Mar 2021 22:15:55
	(b) (4)	

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered '16:12'	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 22:15:55

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:26

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '04 Mar 2021 16:12'	System	04 Mar 2021 22:15:55

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:31:26

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 22:15:42

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:31:26

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered '04 Mar 2021'	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 22:15:42

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:31:26

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered '16:13'	Jessie Downs (b) (4) (b) (4)	04 Mar 2021 22:15:42

US3172406

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:31:26

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:42:20
User entered '04 Mar 2021 16:13'	System	04 Mar 2021 22:15:42

US3172406

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:31:26

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:50
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	16 Feb 2021 21:00:18
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	19 Oct 2020 21:06:12
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
User entered 'USA-US118-2021-mRNA-1273-P301000007'	System	17 Feb 2021 15:26:34
User entered 'New'	(b) (4), (b) (6)	17 Feb 2021 15:26:34

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Patella fracture, LLT: Patella fracture - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 11:28:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 11:28:59
	(b) (4)	
Data point term sent to Coder	System	16 Feb 2021 21:03:28
User entered 'Left knee patella fracture'	Mariete Rendon (b) (4)	16 Feb 2021 21:03:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '31 Jan 2021'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:18:44
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'ae still ongoing' (Site from Safety).	Jessie Downs (b) (4)	25 Feb 2021 20:39:30
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 13:25:08
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	16 Feb 2021 21:03:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 21:03:23

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '1'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '09 Feb 2021'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:18:42
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'pending medical records. ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:39:49
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 13:23:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '12 Feb 2021'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

US3172406

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Not Applicable (NOT APPLICABLE)'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:31:26

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:22:09
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' answered with 'Concomitant medication log was updated' (Site from DM).	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:03:16
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please review and update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 02:15:20
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:18:37
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'pending medical records ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:40:10
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 13:25:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety). Signature has been broken.	(b) (4), (b) (6) (b) (4)	26 Feb 2021 17:18:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:40:52
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'pending medical records ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:40:24
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	25 Feb 2021 13:24:37
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = WILL START REHAB IN 6 WEEKS. Please review and verify if this was already performed. If yes, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:46:23
Query 'Per DM CLR: Narrative = REQUIRING SURGICAL REPAIR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:45:42
User opened query 'Per DM CLR: Narrative = REQUIRING SURGICAL REPAIR. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:45:32
User opened query 'Per DM CLR: Narrative = FALL ON 31JAN2021 . However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 01:45:20
User opened query 'Per CDM: Per you response, please leave query open until medical records have been obtained and the concomitant procedure has been recorded.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 21:50:45
User closed query 'Per DM CLR: Narrative indicates that the subject required surgical repair for this AE. However, there is no corresponding Concomitant Procedure record that match the information. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 21:49:25
User opened query 'PV requery: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:45:11
User opened query 'PV query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:45:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV requery: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:44:24
User opened query 'PV requery: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:44:08
User opened query 'PV requery: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:43:57
User opened query 'PV requery: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 16:43:46
Query 'Per DM CLR: Narrative indicates that the subject required surgical repair for this AE. However, there is no corresponding Concomitant Procedure record that match the information. Please review and update accordingly. Otherwise, clarify.' answered with 'Medical records were requested. Pending to be received.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:04:11
User opened query 'Per DM CLR: Narrative indicates that the subject required surgical repair for this AE. However, there is no corresponding Concomitant Procedure record that match the information. Please review and update accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 02:16:31
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:18:32

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 17:18:28
Query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' answered with 'pending medical records ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:41:20
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'pending medical records ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	25 Feb 2021 20:41:06
User opened query 'PV Query: What was the reason for the fall? (i.e. mechanical, accidental, underlying condition, etc)' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 13:26:18
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 13:24:13
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Left knee patella fracture secondary to fall on 31JAN2021 requiring surgical rpaie and 3 days hospitalization. will start rehab in 6 weeks. will request records for details.'	Mariete Rendon (b) (4) (b) (4)	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Feb 2021 21:03:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:26

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Feb 2021 21:03:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:31:26

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:02:50
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:00:01
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	19 Oct 2020 22:03:36

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 22:02:28
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 22:02:28
	(b) (4)	
Data point term sent to Coder	System	20 Oct 2020 22:01:55
User entered 'TYLENOL'	Mariete Rendon (b) (4)	20 Oct 2020 22:01:20
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'LEFT ARM PAIN AT INJECTION SITE (SOLICITED ADVERSE REACTION) (nOT AN a/e)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '500'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'as needed (PRN)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '19 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 22:01:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:17:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 14:17:05
Data point term sent to Coder	System	19 Nov 2020 14:16:02
User entered 'Tylenol'	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:15:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:15:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'headache, chills, body ache, myalgia, arthralgia, injection site pain (Solicited adverse reaction) (Not an A/E)'	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:15:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '500'	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:15:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:15:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:15:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'three times daily (TID)'	Mariete Rendon (b) (4)	19 Nov 2020 14:15:09
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:15:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:15:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:15:09

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '17 Nov 2020'	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:15:09

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	19 Nov 2020 14:15:09
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	19 Nov 2020 14:15:55
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	19 Nov 2020 14:15:09
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	19 Nov 2020 14:15:55
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	19 Nov 2020 14:15:09
User entered '18 Nov 2020'	Mariete Rendon (b) (4)	19 Nov 2020 14:15:09
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Nov 2020 14:15:09

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User entered '3'	System	19 Nov 2020 14:15:09

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User entered '1'	System	19 Nov 2020 14:15:09

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 01:07:31
User entered '804 (804)'	System	19 Nov 2020 14:15:09

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: OTHER AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: RENIN-INHIBITORS, PRODUCT: ALISKIREN FUMARATE, PRODUCTSYNONYM: TEKTURNA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 19:22:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 19:22:41
	(b) (4)	
Data point term sent to Coder	System	11 Jan 2021 19:21:50
User entered 'tekturna'	Jessie Downs (b) (4)	11 Jan 2021 19:21:27
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'hypertension'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '300/25'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'un UNK 2004'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Jan 2021 19:21:27

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 19:23:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 19:23:40
	(b) (4)	
Data point term sent to Coder	System	11 Jan 2021 19:22:50
User entered 'metropolol'	Jessie Downs (b) (4)	11 Jan 2021 19:22:06
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'hypertension'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '50'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	11 Jan 2021 19:22:06
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'un UNK 2004'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Jan 2021 19:22:06

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 19:27:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 19:27:41
	(b) (4)	
Data point term sent to Coder	System	11 Jan 2021 19:26:53
User entered 'vitamin d'	Jessie Downs (b) (4)	11 Jan 2021 19:26:07
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4)	22 Jan 2021 20:27:22
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	11 Jan 2021 19:26:07
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User closed query 'Per CDM: Response noted. Per CCG Page no-40, Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 18:38:30
Query 'Per CDM: Response noted. Per CCG Page no-40, Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. Thank you.' answered with 'Data was updated. ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	22 Jan 2021 20:27:59
User opened query 'Per CDM: Response noted. Per CCG Page no-40, Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 03:21:07
User entered 'nutritional supplement'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '5000'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Other (OTHER)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:42:07
	(b) (4)	
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	11 Jan 2021 19:26:17
User entered 'units' reason for change: Data Entry Error	Jessie Downs (b) (4)	11 Jan 2021 19:26:17
	(b) (4)	
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	11 Jan 2021 19:26:07
User entered empty.	Jessie Downs (b) (4)	11 Jan 2021 19:26:07
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'every week (QS)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'un UNK 2018'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered '0'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered empty.	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	11 Jan 2021 19:26:07

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL WITH CODEINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 12:16:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 12:16:37
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
Data point term sent to Coder	System	03 Mar 2021 16:03:05
User entered 'TYLENOL (acetaminophen 300mg / codeine 30 mg)' reason for change: Data Entry Error	Jessie Downs (b) (4)	03 Mar 2021 16:02:19
Data point term sent to Coder	System	03 Mar 2021 16:00:58
User entered 'Tylenol'	Jessie Downs (b) (4)	03 Mar 2021 16:00:23
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'left knee fracture - SAE'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered '330' reason for change: Data Entry Error	Jessie Downs (b) (4)	03 Mar 2021 16:02:44
	(b) (4)	
User entered '300'	Jessie Downs (b) (4)	03 Mar 2021 16:00:23
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered '09 Feb 2021'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered '0'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	09 Mar 2021 14:44:52
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Mar 2021 16:00:23

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 16:11:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 16:11:54
	(b) (4)	
Data point term sent to Coder	System	03 Mar 2021 16:02:02
User entered 'Tylenol'	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'left knee pain secondary to fracture - sae'	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered '1000'	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'other (OTHER)'	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'tid / prn'	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered '31 Jan 2021'	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:41:41
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	19 Apr 2021 20:46:03
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	19 Apr 2021 20:46:03
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:41:41
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	19 Apr 2021 20:46:03
	(b) (4)	
User entered '08 Feb 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	19 Apr 2021 20:46:03
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User signature succeeded.	Mark Kutner (b) (4)	09 Mar 2021 14:44:52
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	03 Mar 2021 16:01:25
	(b) (4)	

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User entered empty.	System	03 Mar 2021 16:01:25

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User entered empty.	System	03 Mar 2021 16:01:25

US3172406

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:26

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:49:38
User entered empty.	System	03 Mar 2021 16:01:25

US3172406

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:31:26

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:42:07
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Oct 2020 21:06:19

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered		
'USA-US118-2021-MRNA-1273-P301000007'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'Yes (Y)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:41:09
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'Yes (Y)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'Mark'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'Kutner'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'FL'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:18:59
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
User entered 'US'	System	17 Feb 2021 15:27:36

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	26 Feb 2021 17:19:34
User entered '2'	System	26 Feb 2021 17:19:34
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
User entered '1'	System	17 Feb 2021 15:27:36

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered		
'USA-US118-2021-MRNA-1273-P301000007'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'Yes (Y)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'Yes (Y)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'Mark'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'Kutner'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'FL'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:18:59
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
User entered 'US'	System	17 Feb 2021 15:27:36

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	26 Feb 2021 17:19:34
User entered '2'	System	26 Feb 2021 17:19:34
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
User entered '1'	System	17 Feb 2021 15:27:36

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:31:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
User entered '17/Feb/2021 10:27'	System	17 Feb 2021 15:27:36

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:31:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:18:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:41:09
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 15:27:36

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered		
'USA-US118-2021-MRNA-1273-P301000007'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'Yes (Y)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'Yes (Y)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	23 Feb 2021 14:41:09
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'No (N)'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'Mark'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'Kutner'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 15:27:22
User entered 'FL'	System	17 Feb 2021 15:26:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:18:59
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
User entered 'US'	System	17 Feb 2021 15:27:36

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:26

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	26 Feb 2021 17:19:34
User entered '2'	System	26 Feb 2021 17:19:34
User signature succeeded.	Mark Kutner (b) (4)	23 Feb 2021 14:41:09
	(b) (4)	
User entered '1'	System	17 Feb 2021 15:27:36

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:31:26

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 14:02:34
	(b) (4)	
User entered '26/Feb/2021 11:19'	System	26 Feb 2021 17:19:34

US3172406

Folder: SAE USA-US118-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:31:26

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 14:02:34
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 17:19:34